# EPA'S OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION (OCSPP)

Briefing Materials for Mike Dourson, Nominee for Assistant Administrator

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# Table of Contents

# About the Office of Chemical Safety and Pollution Prevention (OCSPP)

## What We Do

Using sound science, and the rule of law, as a compass, OCSPP's mission is to protect you, your family, and the environment from potential risks from pesticides and toxic chemicals. Through innovative partnerships and collaboration, we also work to prevent pollution before it begins. This reduces waste, saves energy and natural resources, and leaves our homes, schools and workplaces cleaner and safer. OCSPP implements the:

- [ HYPERLINK "https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act" ]
- [ HYPERLINK "https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act" ]
- [ HYPERLINK "https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act" ]
- [ HYPERLINK "https://www.epa.gov/laws-regulations/summary-pollution-prevention-act" ].

## OCSPP Leadership

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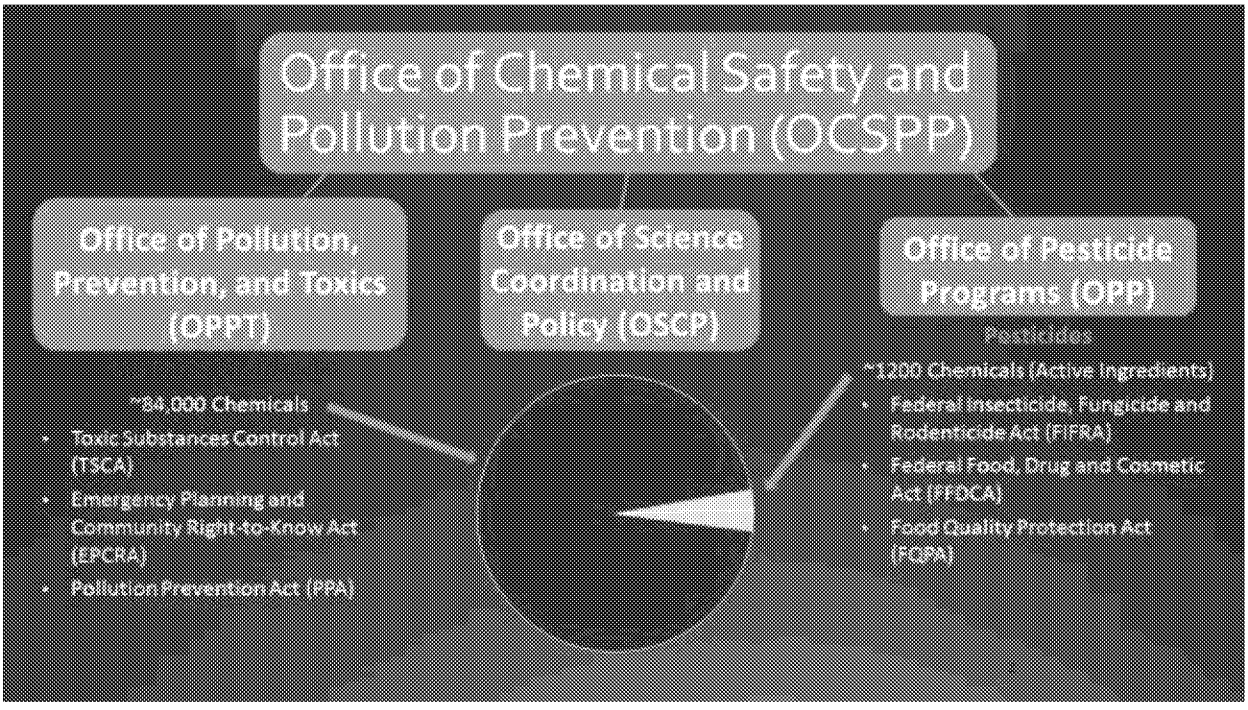
# Overview of Offices, Function and Scope of Authority

## Organization

The Office of Chemical Safety and Pollution Prevention includes the following three program offices:

- [ HYPERLINK "https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp" \l "opp" ]
- [ HYPERLINK "https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp" \l "oppt" ]
- [ HYPERLINK "https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp" \l "oscp" ]



# Office of Pesticide Programs (OPP)

OPP regulates the manufacture and use of all pesticides (including insecticides, herbicides, rodenticides, disinfectants, sanitizers and more) in the United States and establishes maximum levels for pesticide residues in food, thereby safeguarding the nation's food supply. EPA has expanded public access to information about risk assessment and risk management actions to help increase transparency of decision making and facilitate consultation with the public and affected stakeholders.

In addition to our regulatory functions, we provide information and coordinate with partners and stakeholders on issues ranging from worker protection to misuse of pesticides. We participate in a variety of partnerships related to pesticide use, including the Pesticide Environmental Stewardship Program, a voluntary private and public partnership dedicated to reducing pesticide use and risk, and Integrated Pest Management in Schools.

OPP implements the [ HYPERLINK "https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act" ], the [ HYPERLINK "https://www.epa.gov/pria-fees" ], and key parts of the [ HYPERLINK "https://www.epa.gov/laws-regulations/summary-food-quality-protection-act" ], and the [ HYPERLINK "https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act" ].

**Programs and projects managed by the Office of Pesticide Programs**

- [ HYPERLINK "https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks" ]
- [ HYPERLINK "https://www.epa.gov/bedbugs" ]
- [ HYPERLINK "https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/epas-regulation-biotechnology-use-pest-management" ]
- [ HYPERLINK "https://www.epa.gov/endangered-species" ]
- [ HYPERLINK "https://www.epa.gov/ingredients-used-pesticide-products" ]
- [ HYPERLINK "https://www.epa.gov/insect-repellents" ]
- [ HYPERLINK "https://www.epa.gov/managing-pests-schools" ]
- [ HYPERLINK "https://www.epa.gov/mosquitocontrol" ]
- [ HYPERLINK "https://www.epa.gov/pesticide-labels" ]
- [ HYPERLINK "https://www.epa.gov/pesticide-registration" ]
- [ HYPERLINK "https://www.epa.gov/pesticide-reevaluation" ]
- [ HYPERLINK "https://www.epa.gov/pesticide-tolerances" ]
- [ HYPERLINK "https://www.epa.gov/pesp" ]
- [ HYPERLINK "https://www.epa.gov/pets" ]
- [ HYPERLINK "https://www.epa.gov/pollinator-protection" ]
- [ HYPERLINK "https://www.epa.gov/reducing-pesticide-drift" ]
- [ HYPERLINK "https://www.epa.gov/pesticide-worker-safety/agricultural-worker-protection-standard-wps" ]

[ HYPERLINK "https://www.epa.gov/pesticide-contacts/organization-chartcurrent-headquarters-leadership-epa-pesticide-programs" ]

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# Office of Pollution Prevention and Toxics (OPPT)

OPPT manages programs under the Toxic Substances Control Act, the Toxic Release Inventory, and the Pollution Prevention Act. Under these laws, EPA evaluates new and existing chemicals and their risks, collects and publishes data on chemical releases from facilities, and manages a variety of environmental stewardship programs that encourage companies to reduce and prevent pollution. OPPT implements the [ HYPERLINK "https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act" ], the [ HYPERLINK "https://www.epa.gov/laws-regulations/summary-pollution-prevention-act" ] and [ HYPERLINK "https://www.epa.gov/regulatory-information-topic/regulatory-information-topic-toxic-substances" \l "tri" ] of the [ HYPERLINK "https://www.epa.gov/epcra/what-epcra" ].

[ HYPERLINK "https://www.epa.gov/chemicals-under-tsca" ]

**Programs and projects managed by the Office of Pollution Prevention and Toxics**

- [ HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca" ]
- [ HYPERLINK "https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-biotechnology-under-tsca" ]
- [ HYPERLINK "https://www.epa.gov/tsca-import-export-requirements" ]
- [ HYPERLINK "https://www.epa.gov/tsca-screening-tools" ]
- [ HYPERLINK "https://www.epa.gov/tsca-inventory" ]
- [ HYPERLINK "https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca" ]
- [ HYPERLINK "https://www.epa.gov/chemical-data-reporting" ]
- [ HYPERLINK "https://www.epa.gov/p2" ]
- [ HYPERLINK "https://www.epa.gov/greenchemistry" ]
- [ HYPERLINK "https://www.epa.gov/greenerproducts" ]
- [ HYPERLINK "https://www.epa.gov/tsca-cbi" ]
- [ HYPERLINK "https://www.epa.gov/saferchoice" ] (formerly Design for the Environment)
- [ HYPERLINK "https://www.epa.gov/sustainable-futures" ]
- [ HYPERLINK "https://www.epa.gov/toxics-release-inventory-tri-program" ]

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# Office of Science Coordination and Policy (OSCP)

OSCP aims to assure sound scientific decisions are made regarding safe pesticide and chemical management through the management of two statutorily required peer review committees: the Scientific Advisory Panel, under FIFRA, and the Science Advisory Committee on Chemicals, under TSCA. We also coordinate the endocrine disruptor screening program.

**Programs and projects managed by the Office of Science Coordination and Policy**

- [ HYPERLINK "https://www.epa.gov/endocrine-disruption" ]
- [ HYPERLINK "https://www.epa.gov/sap" ]
- Science Advisory Committee on Chemicals (SACC) - [ HYPERLINK "https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0474-0001" ]

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# OCSPP BUDGET OVERVIEW

OCSPP's budget is comprised of 12 "Program Projects." These are the programmatic elements that appear in the Presidents Budget and Congressional appropriations.

OCSPP receives funding for these Program Projects in three Congressional Appropriation Accounts:

- Environmental Programs & Management (EPM) – Primarily Operating funds (e.g. contracts, travel, expenses) and Payroll
- Science & Technology (S&T) – Primarily funds OCSPP/OPP Labs
- State and Tribal Assistance Grants (STAG)

OCSPP is authorized to collect and spend fees under the FIFRA, PRIA, and TSCA:

- FIFRA – Maintenance Fees for Pesticide Re-registrations
- PRIA – Registration Fees for new Pesticide Registrations
    - Authority to collect expiring at end of FY 2017, reauthorization currently on the Hill
- TSCA – Fees for implementing specific TSCA sections authorized by the 2016 TSCA Amendments.
    - Currently developing the rule to collect fees. Fee collection is expected to begin in FY2019.

A majority of OCSPP funding is housed in Headquarters, unlike water, air, and waste programs, there is a small presence in the EPA Regions for the Pesticides and Toxics Programs. Regions provide technical assistance, direct implementation of certain programs, outreach, and administration of OCSPP's Categorical (non-STAG) Grants, which are funded from the EPM account.

## OCSPP FY 2017 Full Time Equivalent Employee Ceiling by Program Office

| OCSPP Program Office | FY 17 FTE Ceiling |
|---|---|
| AA/Immediate Office | 35.8 |
| Office of Pesticide Programs | 635.9* |
| Office of Pollution Prevention and Toxics | 311.1 |
| Office of Science Coordination and Policy | 19.0 |
| Regional Resources | 154.2 |
| **Total OCSPP FTE** | **1,156.0** |

*additional FTE are funded by fees.

## Total OCSPP Related Program Funding: FY 2016 Enacted – FY 2018 President's Budget

| | FY 2016 | | FY 2017 | | FY 2018 | |
|---|---|---|---|---|---|---|
| **Program Project** | **Dollars** | **FTE** | **Dollars** | **FTE** | **Dollars** | **FTE** |
| Pollution Prevention Program | $13,140.0 | 58.1 | $12,091.0 | 58.1 | $0.0 | 0.0 |
| TRI / Right to Know (Includes OEI) | $13,882.0 | 43.5 | $13,932.0 | 43.5 | $8,680.0 | 28.4 |
| Toxic Substances: Chemical Risk Review and Reduction | $58,554.0 | 238.7 | $59,398.0 | 238.7 | $65,036.0 | 240.7 |
| Toxic Substances: Lead Risk Reduction Program | $13,275.0 | 72.8 | $13,175.0 | 72.8 | $0.0 | 0.0 |
| Science Policy and Biotechnology | $1,174.0 | 5.4 | $1,468.0 | 5.4 | $0.0 | 0.0 |
| Endocrine Disruptors | $7,553.0 | 8.9 | $7,260.0 | 8.9 | $0.0 | 0.0 |
| Pesticides: Protect Human Health from Pesticide Risk | $60,937.0 | 418.7 | $58,825.0 | 418.7 | $50,842.0 | 416.5 |
| Pesticides: Protect the Environment from Pesticide Risk | $39,621.0 | 269.3 | $40,673.0 | 269.3 | $34,125.0 | 268.4 |
| Pesticides: Realize the Value of Pesticide Availability | $6,657.0 | 46.5 | $6,728.0 | 46.5 | $6,555.0 | 46.3 |
| Categorical Grant: Pollution Prevention | $4,765.0 | 0.0 | $4,682.0 | 0.0 | $0.0 | 0.0 |
| Categorical Grant: Pesticides Program Implementation | $12,701.0 | 0.0 | $12,481.0 | 0.0 | $8,874.0 | 0.0 |
| Categorical Grant: Lead | $14,049.0 | 0.0 | $13,805.0 | 0.0 | $0.0 | 0.0 |
| **Total OCSPP Programs** | **$246,308.0** | **1,161.9** | **$244,518.0** | **1,161.9** | **$173,112.0** | **1,000.3** |

# CHLORPYRIFOS

## SUMMARY:

On March 29, 2017, EPA issued an order denying a petition from the Pesticide Action Network of North America (PANNA) and Natural Resources Defense Council (NRDC), requesting that the EPA revoke all tolerances (maximum residue levels) in food for the pesticide chlorpyrifos under the Federal Food, Drug, and Cosmetic Act (FFDCA) and cancel all chlorpyrifos registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). USDA scientists supported this determination. The EPA intends to complete the registration review of chlorpyrifos by October 1, 2022. In completing the registration review for chlorpyrifos, the EPA will further evaluate the neurodevelopmental effects reported in epidemiological studies and consider these reports in the context of the animal toxicity data available on chlorpyrifos. Regarding potential ecological concerns, the draft Biological Opinion for chlorpyrifos (as well as malathion and diazinon) is expected from the Services this summer. The Final Biological Opinions are currently due in December 2017.

## BACKGROUND:

- In September 2007, PANNA and NRDC submitted a petition seeking revocation of all tolerances and cancellation of all Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registrations of products containing the insecticide chlorpyrifos.
- Through the pesticide re-evaluation program, the EPA conducted risk assessments in 2011 (preliminary), 2014 (revised after public comment), and 2015 (part of the proposed rule) that incorporated new methodologies as the science has advanced. In October 2015, the EPA proposed to revoke all food residue tolerances for chlorpyrifos.
- The EPA took most of the complex and novel science questions raised in the petition to the FIFRA Scientific Advisory Panel (SAP) for review several times. Specifically, the EPA requested the SAP to review new worker and non-occupational exposure methods, experimental toxicology and epidemiology, risk assessment approaches for semi-volatile pesticides, and the evaluation of a pharmacokinetic-pharmacodynamic model.
- In November 2017, after consideration of the advice received from the FIFRA SAP, EPA issued a revised risk assessment. EPA is currently considering all of the comments received on the draft risk assessments.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- Considering SAP's recommendations, the EPA issued a Notice of Data Availability in November 2016 on a revised human health risk assessment.
- In January 2017, the EPA initiated formal consultation under the Endangered Species Act with the US Fish and Wildlife Service and the National Marine Fisheries Service.
- The EPA issued the order denying the PANNA-NRDC petition on March 29, 2017, based on scientific uncertainty.
- On July 18, 2017, the 9th Circuit Court of Appeals denied a request by PANNA/NRDC to require the EPA to issue a substantive decision on their petition. The court directed that petitioners proceed through the objections process provided under FIFRA.

## HOT ISSUES:

EPA's decision to deny the petition has received considerable attention and is the subject of controversy in the press and on the Hill.

## LEAD OFFICE/REGION:

OCSPP

## OTHER KEY OFFICES/REGIONS:

# DICAMBA

## SUMMARY:

Dicamba is an active ingredient registered for pesticide use as an herbicide. In late 2016, EPA registered a dicamba product designed to control weeds in cotton and soybean plants that have been genetically engineered to resist dicamba (also known as dicamba-resistant corn and soybeans). Monsanto, BASF and DuPont have dicamba end-use products. Since June 2017, the EPA has been receiving reports regarding a high number of crop damage incidents involving dicamba.

## BACKGROUND:

- Reports of crop damage began June 13, 2017. Initial reports came from Arkansas, Missouri, Mississippi, and Tennessee. As the growing/use season proceeds, recent reports have been expanding into more northern states (Iowa, Nebraska, and Kansas).
- The underlying causes of the various damage incidents are not yet clear. EPA is currently reviewing the available information.
- When the product was registered in 2016, EPA estimated exposure to non-target crops from pesticide drift/movement. To help prevent drift/movement, EPA required precautions and product use limitations.
- EPA also limited the registration to two years to allow for opportunity to reassess use and either let it expire or easily make necessary changes in the registration if there are problems with resistant weeds or pesticide drift.
- Despite approval of new dicamba products with drift reduction agents and further use restrictions, which were set in place prior to the 2017 growing season, many states have reported high numbers of dicamba complaints.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- The Office of Pesticide Programs (OPP) has met with state lead agency representatives, extension service experts, and the registrants to learn more about the scope and source(s) of the damage, participation of growers in training programs prior to application, and to identify potential measures that could be used to prevent further damage. We will continue to work with affected stakeholders.
- On July 13, OPP held a teleconference with state experts from Arkansas, Georgia, Indiana, Mississippi, Missouri, Nebraska, and Tennessee to discuss the observed crop damage.
- In response to the incidents reported, three states (Arkansas, Missouri, and Tennessee) have taken additional steps to further restrict the use of dicamba.

## HOT ISSUES:

Some states are reacting to crop damage reports by banning or further restricting uses of dicamba.

## LEAD OFFICE/REGION: OCSPP/OPP OTHER KEY OFFICES/REGIONS: N/A

# GLYPHOSATE

## SUMMARY:

Glyphosate (RoundUp) is a widely used herbicide that controls broadleaf weeds and grasses. EPA is currently re-evaluating the safety of glyphosate through our registration review program. This re-evaluation process occurs every 15 years and is mandated by federal law. In December 2016, EPA convened its FIFRA Scientific Advisory Panel (SAP) to review and solicit comments on our findings that glyphosate is not likely to be carcinogenic to humans at doses relevant for human health risk assessment. Once EPA has reviewed the SAP report and made any appropriate changes to our risk assessment, we intend to release the draft human health and ecological risk assessments for a 60-day public comment period in the Federal Register.

EPA is currently scheduled to complete the draft risk assessments no later than 2017. After consideration of the public comments on the draft risk assessments, EPA will determine whether any risk management is needed. We intend to complete our evaluation (including an ESA assessment), consistent with the statutory deadline for registration review in 2022.

## BACKGROUND:

- The EPA initiated registration review for glyphosate in 2009. The agency is in the process of completing the draft risk assessments supporting this review. The upcoming draft risk assessments will incorporate the results of endocrine screening analysis and the potential effects on monarch butterflies, as well as consider the 2015 International Agency for Research on Cancer (IARC) report classifying glyphosate as a probable cancer causing agent.
- Subsequent to IARC's 2015 report, various international regulatory agencies have concluded that glyphosate does not cause cancer. In April 2016, the EPA inadvertently published (to the public docket) a memorandum from its Cancer Assessment Review Committee (CARC), which classified glyphosate as "not likely to be carcinogenic to humans." This report was later redacted from the docket because the risk assessment was incomplete (EPA is currently working to complete the assessment).
- In December 2016, the EPA held a FIFRA Scientific Advisory Panel (SAP) meeting to discuss the carcinogenic potential of glyphosate. The agency proposed to classify glyphosate as "not likely to be carcinogenic to humans." The EPA received SAP's recommendations in March 2017, and is currently reviewing the report.
- Although the 2015 IARC reached the conclusion that glyphosate is a probable cancer causing agent, the European Food Safety Authority concluded in November 2015 that glyphosate is unlikely to pose a carcinogenic hazard to humans. In May 2016, the Joint Food and Agriculture Organization Meeting on Pesticide Residues (JMPR) also concluded that glyphosate was unlikely to pose a carcinogenic risk to humans from exposure through the diet. Similar decisions have been made by regulatory agencies in numerous countries including Canada, Germany, Japan, New Zealand, and Australia.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

None

| HOT ISSUES: |
| --- |
| The cancer classification of glyphosate has garnered considerable public attention. |

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
| --- | --- |
| OCSPP | ORD |

# FIFRA AND ENDANGRED SPECIES ACT

## SUMMARY:

The EPA is collaborating with the Services to develop interim scientific approaches and create a sustainable process for completing consultations that meet requirements of both statutes. The EPA aims to streamline the process to a point where it is protective of species, timely for FIFRA registration review decisions, feasible within the agencies' resource constraints, and transparent to the public.

## BACKGROUND:

- Historically, the EPA and the Services (Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS)), have been unable to reach consensus on a risk assessment approach.
- In an April 2013 report, the National Academy of Sciences (NAS) provided recommendations to the EPA, the Services, and USDA on a common approach for assessing the risks of pesticides to endangered species.
- EPA's biological evaluations (BEs) implementing these methods are the first step in the consultation process. The Services may then adopt, modify, or reject EPA's conclusions when developing biological opinions (BiOps) to determine if species are jeopardized. The EPA may then take regulatory action to address such risks.
- EPA and the Services have entered into settlement agreements, resolving 4 lawsuits and allowing the agencies to focus on nationwide consultations for 5 pesticides (chlorpyrifos, diazinon, malathion, carbaryl, and methomyl). Final BiOps for chlorpyrifos, diazinon and malathion are due in December 2017. Final BiOps for carbaryl and methomyl are due in December 2018. EPA and FWS have also set schedules for the next 4 nationwide pesticide consultations (atrazine, glyphosate, simazine, and propazine). EPA plans to complete final BEs in June 2020. FWS will complete final BiOps in June 2022.
- Several additional ESA lawsuits are pending against EPA, including challenging new chemical registration decisions (cyantraniliprole, flupyridifurone, bicyclopyrone, benzovindiflupyr, and coupron couprous iodide); Ellis v. Keigwin (clothianidin and thiamethoxam) and the Megasuit. There was a recent ruling for cyantraniliprole, remanding the registration without vacatur to EPA to initiate consultation under the ESA.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

In January 2017, the EPA issued the first ever nation-wide draft BEs for chlorpyrifos, diazinon, and malathion. On April 13, 2017, registrants for these pesticides sent letters to the political leadership of the EPA and the Services requesting the EPA withdraw the BEs, the Services stop work on their BiOps, and modify the settlement agreements to allow more time to complete consultation. The EPA is considering the request.

## HOT ISSUES:

**Congressional Inquiries:** The House Committees on Natural Resources and Agriculture and the Senate Committees on Agriculture and Environment and Public Works have previously expressed interest in the EPA's progress towards implementing the NAS report recommendations and completion of the BiOps. Under court-ordered settlements, the Services are to issue BiOps for chlorpyrifos, diazinon, and malathion by December 2017, and for carbaryl and methomyl by December 2018. For the Services to meet these settlement dates the EPA initiated consultation in January 2017, by issuing BEs for the first three pesticides.

## LEAD OFFICE/REGION:

OCSPP

## OTHER KEY OFFICES/REGIONS:

# POLLINATORS

## SUMMARY:

Pollinator protection is a priority for the EPA, given that bee pollination and insect control are essential to the success of agriculture. A complex set of stressors has been associated with honey bee declines, including loss of habitat, parasites and disease, genetics, poor nutrition, bee management practices, and pesticide exposure. No single factor has been identified as the cause. The EPA has been working to protect bees and other pollinators from pesticide exposures, while continuing to make regulatory decisions under the risk-benefit parameters of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

## BACKGROUND:

- Pollinators are critical to our nation's economy, food security, and environmental health. Bee pollination and insect control are essential to the success of agriculture. Honey bee pollination alone adds more than $15 billion in value to agricultural crops each year.

- In January 2016, the EPA, in collaboration with our regulatory partners in Canada and California, released for public comment, our preliminary pollinator risk assessment for imidacloprid, a neonicotinoid pesticide. This assessment followed guidance describing a tiered process for assessing risk to bees from pesticides that EPA developed with Canada's PMRA input and issued in 2014. Additional assessments for the neonicotinoids, clothianidin, dinotefuran and thiamethoxam, using this same guidance and also in collaboration with our regulatory partners, were released in January 2017. EPA is continuing its review of the data to determine the likelihood of adverse effects to honey bee colonies and plans to complete reviews of these neonicotinoids in 2018.

- In January 2017, the EPA announced a policy that all chemicals that are acutely toxic to pollinators and are labeled for use on crops that may use contract pollination services, applications at bloom are prohibited if the application rates exceed the EPA's level of concern.

- In January 2017, the EPA hosted an international workshop on assessing exposure to native pollinators to determine if our conservative assessments are adequately protective.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

None

## HOT ISSUES:

Lawsuits and petitions brought by the Center for Food Safety (CFS) and others have been filed regarding the registration of the neonicotinoids and, more recently, over seeds that are coated with neonicotinoid pesticides. These petitions are currently in review.

## LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

| | |
|---|---|
| OCSPP/OPP | CA DPR; Canada's PMRA |

# CONTROLING CEROSPORA IN SUGAR BEETS

## SUMMARY:

In late March and early April 2017, the states of Michigan, Minnesota, and North Dakota submitted to EPA emergency exemption (FIFRA Section 18) requests for the use of the fungicide chlorothalonil to control Cercospora in sugar beets. In July 2017, EPA informed the states that the agency was unable to make a safety finding for the use of chlorothalonil on this crop and denied the emergency exemption requests.

## BACKGROUND:

- EPA is currently re-evaluating the safety of chlorothalonil as part of the statutorily-mandated registration review program. As part of this re-evaluation, in March 2012, EPA identified several data gaps which preclude the Agency from being able to make the required safety finding under the FFDCA to set a tolerance for the use of chlorothalonil on sugar beets.

- The registrants for chlorothalonil are in the process of generating the necessary data to support the continued registration of this fungicide. EPA expects to receive the required studies later in 2017. EPA will review these data to determine if a different determination can be made for the 2018 growing season.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- EPA has had several conversations with state agricultural agencies and cooperative extensions to try to identify potential alternatives to meet the pest control needs of sugar beet growers for the 2017 growing season.

## HOT ISSUES:

**Congressional Inquiries:**
**Date:** May 09, 2017; **Congressperson:** U.S. Representative Kevin Cramer
**Date:** May 11, 2017; **Congressperson:** U.S. Representative John Moolenaar; U.S. Representative Collin Peterson; U.S. Representative Kevin Cramer; U.S. Representative Paul Mitchell; U.S. Representative Dan Kildee
**Summary:** Letters in strong support of the Section 18 requests made by the North Dakota Department of Agriculture, Minnesota Department of Agriculture, Michigan Department of Agriculture for the emergency use of chlorothalonil on sugar beets.

**Date**: May 2017, **Congressperson**: Senator Stabenow's staff
**Summary**: Briefing on status of the section 18 requests and the Agency's inability to make the required safety finding for these requests.

## LEAD OFFICE/REGION:

OCSPP

## OTHER KEY OFFICES/REGIONS:

# WORKER PROTECTION STANDARD RULE

## SUMMARY:

In February 2017, the National Association of State Departments of Agriculture (NASDA) petitioned the EPA to extend the implementation of all revised provisions of the Worker Protection Standard Rule (WPS) until at least January 2018. After careful evaluation, the agency believes it appropriate to grant the request to extend the implementation of all revised provisions of the WPS until the necessary guidance and training have been completed to allow state lead pesticide agencies time to successfully implement the rule changes. The EPA will soon begin the regulatory process to formally extend the compliance date for all revised provisions of the WPS.

## BACKGROUND:

- The Worker Protection Standard seeks to protect and reduce the risks of injury or illness to agricultural workers (those who perform hand-labor tasks in pesticide-treated crops, such as harvesting, thinning, pruning) and pesticide handlers (those who mix, load and apply pesticides), resulting from use and contact with pesticides on farms, forests, nurseries and greenhouses.

- The EPA issued the final rule in November 2015, establishing staggered compliance dates for implementation of the changes to the Agricultural Worker Protection Standard. The majority of the new requirements went into effect on January 2, 2017; the remaining requirements are scheduled to go into effect on January 2, 2018.

- In late 2016, NASDA and the American Farm Bureau Federation filed a petition seeking a delay in the implementation of the revised Worker Protection Standard. In January 2017, the EPA denied the petition.

- In February 2017, the National Association of State Departments of Agriculture (NASDA) submitted a new petition requesting EPA postpone the compliance date to at least January 2, 2018 or until adequate compliance tools have been completed and states have the necessary tools, time and resources to implement the rule changes and provide compliance assistance to the regulated community.

- On May 11, 2017, EPA granted the petition and committed to beginning the regulatory process to formally extend the compliance date for all revised provisions of the WPS. This regulation is needed to adjust the compliance date.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

None

## LEAD OFFICE/REGION:

## OTHER KEY OFFICES/REGIONS:

# PESTICIDE APPLICATOR CERTIFICATION AND TRAINING RULE

## SUMMARY:

Certification and training programs, approved by the EPA, are administered by the states and ensure that applicators are properly trained and competent to apply restricted use pesticides, the most acutely toxic pesticides registered by the EPA. The EPA issued the final rule on January 4, 2017. Since its issuance, the agency has delayed the effective date of the rule to May 22, 2018, in order to consider whether further revisions should be made before the rule becomes effective. The EPA understands the critical role that states play in implementing the C&T program and are committed to working with our state partners to ensure a protective, yet flexible, certification and training standard.

## BACKGROUND:

- January 4, 2017, EPA published the final rule revising the certification rule, with a multi-year process for state plans development and EPA approvals - effective date March 6, 2017.
- Several organizations, including the National Association of State Departments of Agriculture, the Association of American Pesticide Control Officials, National Pest Management Association, and National Agricultural Aviation Association, have expressed support for the final rule.
- Notwithstanding this overall support and appreciation for the changes the EPA made in the final rule, many of these organizations have requested that the EPA extend the effective date of the rule until the EPA has:
    - Delivered adequate enforcement guidance, educational materials, and training materials;
    - Provided resources necessary to implement the revised rule; and
    - Made revisions to address concerns about the minimum age restrictions.
- January 20, 2017, "Regulatory Freeze Pending Review" has issued to give newly arrived Agency officials the opportunity to conduct a substantive review of certification rule – effective date moved several times to May 22, 2018.
- Executive Order on Regulatory Reform activity raised general and specific issues regarding the rule

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- On June 2, 2017, EPA extended the effective date of the rule to May 22, 2018.
- A group of farmworker advocacy groups have sued EPA in District court for alleged violations of the Administrative Procedure Act during the rulemaking that postponed the effective date of the certification rule until May 2018.

## HOT ISSUES:

- Consortium of worker advocate groups sued EPA Administrator in 9th Circuit Court and in District Court for administrative procedures act violations.

## LEAD OFFICE/REGION: OCSPP/OPP OTHER KEY OFFICES/REGIONS:

# PRIA 4

## SUMMARY:

The EPA strongly supports the Pesticide Registration Improvement Act (PRIA) 4 and anticipates immediate implementation of the amended law. PRIA 4 brings together a coalition of divergent interests that permits market access of pesticides, benefitting both the pesticides and agricultural industries, while safeguarding the environment and human health. If PRIA 4 is not passed by September 30, 2017, when PRIA 3 sunsets, pesticide applications will no longer be subject to decision time periods. The two-year sunset provision specifies fees be reduced in the first year by 40% below the levels in effect during FY2017, and by 70% in the second year. After two years, fee requirements are terminated. In addition, EPA would no longer be able to collect maintenance fees to support the statutorily-mandated registration review program.

## BACKGROUND:

- PRIA has benefitted from a broad coalition of stakeholder groups representing seven pesticide industry trade groups and two non-governmental organizations. This stakeholder support has paved the way to expedited approval processes in Congress to pass the original law and its amendments to extend.
- PRIA establishes a fee for service framework that charges applicants based on the type and complexity of the activity requested. It also holds the EPA to mandatory time frames for reviewing and making decisions on these actions.
- The fees fund a portion of the EPA's pesticides registration and registration review activities. PRIA 4 is estimated to bring in $17 million per year on average, which helps support staff plus other expenses related to pesticide registration.
- PRIA 4 extends the authorization to collect maintenance fees, at $31M/yr through FY'20. These fees supplement pesticide reevaluation activities, review of substantially similar new registrations and amendments, and review of inert clearances. There are two set-asides specified: one for Good Laboratory Practice (GLP) inspections and the other for development of product performance guidance and rulemaking for invertebrate pests of significant public health importance.
- PRIA allows partial fee waivers for small businesses and exempts federal and state government entities from fee requirements. Applications supported by the IR-4 Project, a USDA-funded program which supports the availability of pest management tools for growers of minor use crops, are likewise exempt from fee requirements. Since PRIA initially became law in March 2004, the EPA has approved over 20,000 pesticide applications, meeting or beating mandated due dates for over 98% of those actions.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- H.R. 1029 was introduced in February, 2017 and was unanimously passed in the House on March 20, 2017. On June 29, 2017, the Senate Agriculture Committee unanimously voted in favor of extending authorization of PRIA for an additional 3 years.

## LEAD OFFICE/REGION: OCSPP/OPP  OTHER KEY OFFICES/REGIONS:

# ACTIONS TO CONTROL ZIKA

## SUMMARY:

The spread of the Zika virus, mainly through mosquitoes, throughout the continental U.S. and territories, is an ongoing and highly visible public health emergency. Through proper mosquito prevention, control and integrated pest management (IPM) at the federal, state, local and household levels, the spread of the Zika virus can be slowed in the U.S.

EPA is continuing to work on the evaluation of pesticides that are approved for use in mosquito control. These evaluations are part of EPA's regular pesticide registration review process. Naled and malathion are two pesticides currently undergoing this evaluation process and both are used by mosquito control districts for aerial and ground spraying to control adult mosquitos.

## BACKGROUND:

- The Zika virus has had the biggest impact in Puerto Rico and other island territories to date. Travel related cases have now been identified in 49 states (none in Alaska).
- The Centers for Disease Control and Prevention is the lead federal agency for responding to the Zika virus. EPA supports CDC, providing expertise in integrated pest management, pesticide registration and use, and cleanup of environmental contamination in indoor and outdoor areas. EPA is focused on appropriate pesticide use, including technical assistance on wide-area spraying, residential treatments, and any potential new product registrations or emergency exemptions. In order to address public health concerns, EPA is providing technical assistance and communications support to prevent pesticide misuse and overuse.
- EPA has approved five emergency exemptions for pesticide products to be used for vector control: Four were issued to CDC to help control mosquito populations. One was issued to the Department of Defense to help them comply with other countries' requirements to disinfect aircrafts coming from countries with Zika transmission.
- EPA conducted a comprehensive review of naled in 2002, as part of its reregistration process. This re-evaluation relied on a wealth of naled-specific toxicity and exposure data, which were used to assess potential dietary, drinking water, occupational and residential risks. Since that time, additional toxicity and exposure studies specific to the naled mosquito-control uses have been conducted. These data are currently under EPA review and will be incorporated into a revised risk assessment, which is being developed as part of the agency's routine registration review process. EPA plans to release for public comment an updated naled mosquito assessment before the end of 2017.
- In 2016, EPA made available for public comment the draft malathion human health risk assessment because the draft risk assessment indicated a potential risk for children when malathion is applied aerially to kill mosquitos. EPA provided mosquito control professionals with advice on how to reduce exposures to protect human health when using malathion as an aerial spray. After consideration of public comments, EPA will propose any necessary risk mitigation decisions and associated label changes. The agency expects to reach a decision in 2017.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

None

## HOT ISSUES:

**Congressional Inquiry: Date**: July 6, 2017; **Congressperson**: U.S. Senator Marco Rubio
**Summary**: How safe is naled, considering it has been recommended for use by Miami-Dade County's to prevent the spread of Zika and what is EPA's role in approving the use of naled.

**Press Inquiries: Date**: June 28, 2017; **Media Outlet**: WLRN/Miami Herald News (radio)
**Question:** Provide existing agency research on naled.

**Date**: June 9, 2017**; Media Outlet**: CNN (web)
**Question**: Agency response to University of Michigan naled study.

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
|---|---|
| OCSPP | Regions 2 and 4, OITA, OEJ |

# EMERGING BIOTECHNOLOGY TO CONTROL MOSQUITOS

## SUMMARY:

The EPA is currently reviewing registration requests submitted by MosquitoMate for Wolbachia mosquitos. The EPA is also involved in discussions with the registrant, Oxitec, and the FDA regarding oxitec mosquitos. Oxitec's genetically engineered mosquitos and MosquitoMate's Wolbachia mosquitoes are emerging biotechnology pesticides that could be used to combat the spread of mosquito-borne diseases, such as Zika.

## BACKGROUND:

- The EPA registers biopesticides, which include alterations of mosquito species to reduce mosquito populations. Two technologies (one action pending with EPA, the other is anticipated) involve release of sterilized male mosquitos. When the altered mosquitos are released and mate with wild female mosquitos, the offspring are not viable.

- One technique introduces Wolbachia bacteria, found naturally in many insect species, into male mosquitos. The EPA is reviewing MosquitoMate's Wolbachia ZAP *Aedes albopictus* pesticide registration application and intends to make a decision in late FY17 or early FY18.

- Another technique involves genetically engineered *Aedes aegypti* mosquitoes. "Oxitec" mosquito is currently regulated by the FDA as a new animal drug under the Federal Food, Drug, and Cosmetic Act and has yet to be approved for general use. FDA has proposed to transfer jurisdiction to the EPA through a published draft guidance document. While awaiting the anticipated jurisdiction change, the EPA can accept an Oxitec application for a pesticide experimental use permit and for an emergency exemption (Section 18).

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- In June 2017, EPA extended the time and added test sites for an existing experimental use permit (EUP) to evaluate the *Wolbachia* bacteria's effectiveness in suppressing *Aedes aegypti* mosquitoes. This permit allows MosquitoMate, Inc., to test a potential new tool to fight mosquitoes at sites in Fresno and Orange Counties in California, Monroe, Lee, and Miami-Dade Counties in Florida, and Harris County in Texas.

- The EUP, originally issued to the University of Kentucky's Department of Entomology in October 2015 for limited testing in Fresno County, California, was extended in September 2016 to add testing in Lee County in Florida. The current permit will allow MosquitoMate, Inc., to continue the development of this new tool.

## HOT ISSUES:

## LEAD OFFICE/REGION: OCSPP/OPP OTHER KEY OFFICES/REGIONS:

# CITRUS GREENING

## SUMMARY:

The EPA is committed to supporting researchers, producers and state personnel in efforts to help control citrus greening, a devastating crop disease. In 2017, the EPA responded to the state of Florida on their FIFRA Section 18 emergency use requests by re-authorizing the use of oxytetracycline and streptomycin products on citrus trees for this season. The EPA also re-authorized the emergency use of clothianidin, an insecticide that can help control the insect vector of this disease. In the past years, the EPA has prioritized and registered several new insecticides for citrus (i.e., flupyradifurone and cyantraniliprole) and has approved and supported a number of state registration actions from Florida under the FIFRA Section 24(c) program.

## BACKGROUND:

- Citrus Greening, also known as Huanglongbing (HLB), is caused by a bacterial pathogen transferred from an infected plant during the feeding activities of an insect pest called the Asian citrus psyllid. HLB was first identified in Florida in 2005. By 2007, the disease had spread through all 34 citrus-producing counties in the state. The onset of symptoms from HLB occur over time and are progressive, starting with reduced fruit yield and quality, and leading eventually to the tree's death. HLB is considered the most serious citrus disease worldwide.

- Florida's citrus supply is critically low and may become insufficient to sustain its juice-processing infrastructure. Orange production has declined from 226.2 million boxes in 1996-1997 to 96.7 million boxes in 2014-2015. Further declines are expected. HLB is believed to cost the Florida citrus industry approximately $300 million/year.

- In July 2017, the California Department of Food and Agriculture and the United States Department of Agriculture confirmed the detection of citrus greening in Riverside County, California.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- The EPA is participating in an important research initiative run by USDA on HLB known as the Multi-Agency Coordination System, a program that funds research to develop tools to control HLB The EPA issued experimental use permits (EUPs) to investigate the efficacy of pinach defensin antimicrobial peptides in targeting the bacterial pathogen causing HLB.

- The EPA continues to coordinate with USDA/APHIS on these field tests as well as other smaller-scale biotech field tests investigating control methods for citrus greening.

## HOT ISSUES:

None

## LEAD OFFICE/REGION: OCSPP/OPP OTHER KEY OFFICES/REGIONS:

# RNAi

## SUMMARY:

"RNAi corn" is an emerging technology that provides an important tool for farmers to help combat corn rootworm resistance in crops altered with Bacillus thuringiensis (Bt). Corn rootworm is a devastating corn pest that has developed resistance to several other pesticides. Corn growers are facing problems of resistance to corn rootworm in some of their Bt-treated crops. RNAi corn provides a new tool for corn growers to fight the corn rootworm and has undergone independent scientific peer review.

## BACKGROUND:

- RNAi, which refers to interference of RNA genes, works as a pesticide by silencing the activity of a targeted gene. Commercial registrations of RNAi-based plant-incorporated protectant (PIP) crops to date have targeted plant pathogens, such as the plum pox virus. MON 87411 is the first RNAi-based PIP to target an insect pest.
- Controlling corn rootworm is a major challenge for many corn growers, and infestations frequently result in significant yield losses to corn crops. Corn rootworm has been referred to as the "billion-dollar pest" because the U.S. Department of Agriculture estimated that the insect can collectively cost corn growers in the United States over a billion dollars in terms of control costs and yield losses.
- PIPs are plants that have genes inserted causing the plants to produce a pesticide inside their own tissue. When plants are genetically modified to produce pesticides in this manner they are regulated by the EPA.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- In June 2017, EPA registered four products containing a new and innovative plant-incorporated protectant (PIP) called SMARTSTAX PRO that will help U.S. farmers control corn rootworm.

## HOT ISSUES:

None

## LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP

# OFFICE OF PESTICIDE PROGRAMS' LABORATORIES

## SUMMARY:

The Office of Pesticide Programs operates two laboratories at the EPA's Environmental Science Center in Fort Meade, Maryland. These laboratories provide essential support for the registration and re-evaluation of conventional and public health pesticides and expertise in the event of emerging threats.

## BACKGROUND:

- The Office of Pesticide Programs operates a microbiology lab and a chemistry lab. Both of these laboratories ensure that registrants have standardized methods to register their products, opening the door for market access.
- The microbiology lab is the only federal lab that develops and standardizes test methods to measure the efficacy of antimicrobial pesticides (disinfectants) against human and animal pathogens. The microbiology lab also provides technical expertise to other federal agencies and states when emerging pathogens arise, for example Ebola, avian flu and *Candida auris*.
- The microbiology lab is the only EPA laboratory with a Biosafety Level 3 certification under the Federal Select Agent program, which enables the lab to analyze for anthrax during an emergency and to evaluate the efficacy of products for decontamination and remediation.
- The chemistry lab reviews tarp fumigant packages for manufacturers so growers can have buffer zone credits and bystanders can be protected from exposure to volatile pesticides. The chemistry lab also collects and maintains reference standards for registered pesticides and their metabolites and degradates that are legally required.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

None

## HOT ISSUES:

None

## LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP

# 2016 AMENDMENTS TO THE TOXIC SUBSTANCES CONTROL ACT (TSCA)

## ISSUE/TOPIC:

What changes were made to TSCA in the 2016 amendments?

## BACKGROUND:

The following provides a brief overview of the key provisions in the Frank R. Lautenberg Chemical Safety for the 21st Century Act for:

- Existing chemicals;
- New chemicals;
- Confidential business information;
- Source of sustained funding;
- Federal-state partnership; and
- Mercury export and disposal.

## EXISTING CHEMICALS

- Chemical Assessments
  - Prioritization
    - EPA must establish a risk-based process to determine which chemicals it will prioritize for assessment, identifying them as either "high" or low" priority substances.
      - High priority – the chemical may present an unreasonable risk of injury to health or the environment due to potential hazard and route of exposure, including to susceptible subpopulations
      - Low priority – the chemical use does not meet the standard for high-priority
  - Risk Evaluations
    - High priority designation triggers a requirement and deadline for EPA to complete a risk evaluation on that chemical to determine its safety
    - Low priority designation does not require further action, although the chemical can move to high-priority based on new information
    - Deadlines:
      - First 180 days – EPA must have 10 ongoing risk evaluations
      - Within 3.5 years – EPA must have 20 ongoing risk evaluations
  - Risk-Based Evaluations to determine "unreasonable risk"
    - Chemicals are evaluated to determine whether a chemical use poses an "unreasonable risk"
      - Risk evaluation excludes consideration of costs or non-risk factors
      - Must consider risks to susceptible and highly exposed populations
  - Action to address unreasonable risks
    - When unreasonable risks are identified, EPA must take final risk management action within two years, or four years if extension needed
    - Costs and availability of alternatives considered when determining appropriate action to address risks

        - Action, including bans and phase-outs, must begin as quickly as possible but no later than five years after the final regulation
    - Manufacturer-requested assessments
        - Manufacturers can request that EPA evaluate specific chemicals, and pay the associated costs as follows:
            - If on the TSCA Workplan, manufacturers pay 50% of costs
            - If not on the TSCA Workplan, manufacturers pay 100% of costs
        - These assessments must account for between 25-50% of the number of ongoing risk evaluations for high-priority chemicals, but do not count towards the minimum 20 ongoing risk evaluation requirement

Chemical Testing Authority

Expands authority to obtain testing information for prioritizing or conducting risk evaluations on a chemical, and expedites the process with new order and consent agreement authorities

Promotes the use of non-animal alternative testing methodologies

Persistent, Bioaccumulative, and Toxic (PBT) Chemicals

New fast-track process to address certain PBT chemicals on the TSCA Workplan

- Risk evaluation not needed, only use of and exposure to chemical are assessed
- Action to reduce exposure to extent practicable must be proposed no later than three years after the new law and finalized 18 months later.
- Additional requirements for PBTs in the prioritization process for assessments

## NEW CHEMICALS

- Pre-Manufacture Review of New Chemicals
    - New requirement that EPA must make an affirmative finding on the safety of a new chemical before it is allowed into the marketplace
        - EPA can take a range of actions to address potential concerns including ban, limitations, and additional testing on the chemical

## CONFIDENTIAL BUSINESS INFORMATION

- Establishes new substantiation requirements for certain types of confidentiality claims from companies
- Requires that EPA review and make determinations on all new confidentiality claims for the identity of chemicals and a subset of other types of confidentiality claims
- EPA must review past confidentiality claims for chemical identity to determine if still warranted

## SOURCE OF SUSTAINED FUNDING

- Allows EPA to collect up to $25 million annually in user fees from chemical manufacturers and processors when they:
    - Submit test data for EPA review
    - Submit a premanufacture notice for a new chemicals or a notice of new use
    - Manufacture or process a chemical substance that is the subject of a risk evaluation; or
    - Request that EPA conduct a chemical risk evaluation
- New fees will defray costs for new chemical reviews and a range of TSCA implementation activities for existing chemicals

## FEDERAL-STATE PARTNERSHIP

- Preservation of State Laws
  - States can continue to act on any chemical, or particular uses or risks from a chemical, that EPA has not yet addressed
  - Existing state requirements (prior to April 22, 2016) are grandfathered
  - Existing and new state requirements under state laws in effect on August 31, 2003, are preserved
  - Preserves states environmental authorities related to air, water, waste disposal and treatment
  - States and federal government can co-enforce identical regulations
- Preemption of State Laws
  - State action on a chemical is preempted when:
    - EPA finds (through a risk evaluation) that the chemical is safe, or
    - EPA takes final action to address the chemical's risks
  - State action on a chemical is temporarily "paused" when EPA's risk evaluation on the chemical is underway, but lifted when EPA:
    - completes the risk evaluation, or
    - misses the deadline to complete the risk evaluation
- Exemptions
  - States can apply for waivers from both general and "pause" preemption
  - If certain conditions are met, EPA MAY grant an exemption from general preemption, and MUST grant an exemption from pause preemption

## MERCURY EXPORT AND DISPOSAL

- Amends requirements of the Mercury Export Ban Act (MEBA) and addresses Dept. of Energy's (DOE) responsibility to designate a long-term storage facility
  - If the facility is not operational by 1/1/2020, DOE must accept title to and pay for permitting and storage costs for mercury accumulated in accordance with MEBA prior to that date
- Requires that EPA create an inventory of supply, use, and trade of mercury and mercury compounds; and prohibits export of certain mercury compounds

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
|---|---|
| OCSPP/OPPT | |

# TSCA IMPLEMENTATION ACTIVITIES

## ISSUE/TOPIC:

EPA's Implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act

## BACKGROUND:

- The Frank R. Lautenberg Chemical Safety for the 21st Century Act, signed into law on June 22, 2016, made a host of transformative changes to the Toxic Substances Control Act (TSCA) that strengthen the EPA's ability to identify and address chemical risks. The EPA promptly began the work of implementing the new law, which became immediately effective, and is continuing to make significant progress in carrying out its requirements.
- The EPA is implementing the numerous new and expanded requirements under TSCA enacted and made immediately effective by the Lautenberg Act. The agency has met and continues to be on track for meeting critical initial statutory deadlines, including the framework rules and the first 10 risk evaluations.
- The EPA is working aggressively to address the new chemicals backlog, including increased staffing and policy changes. Throughput rates are expected to return to normal by August 2017.
- The EPA will continue to seek input from stakeholders on critical implementation elements of TSCA as amended. Since June 2016, EPA has held an unprecedented number of public meetings seeking to hear from affected entities. Input from these meetings and other stakeholder discussions has helped shape the agency considerations.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- Final Active/Inactive Inventory Reporting Rule required by June 2017
  - ✓ Final Rule Published June 22, 2017

- Final Prioritization Process Rule required by June 2017
  - ✓ Final Rule Published June 22, 2017

- Final Risk Evaluation Process Rule required by June 2017
  - ✓ Final Rule Published June 22, 2017

- Initial 10 Risk Evaluations
  - ✓ Identified First 10 Chemicals for Risk Evaluation
  - ✓ Final Scopes Published June 22, 2017

-Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations
  - ✓ Guidance Published June 22, 2017

-Science Advisory Committee established by June 2017
  - ✓ Charter established, 18 members appointed

## UPCOMING/ONGOING ACTIVITIES:

### NEW CHEMICALS

- Continuing work to eliminate the backlog of new chemical submissions
- Development of "Points to Consider" document to increase quality of submissions and efficiency of EPA review

- Public meeting to get additional feedback planned for Fall 2017

## "PRE-PRIORITIZATION"

- Proposed a phase for gathering/developing chemical information and identifying potential candidates for prioritization before initiating the prioritization process for a particular chemical
- Based on public comments received, this phase was excluded from the final rule
- OCSPP committed to further public discussion beginning Fall 2017

## PRIORITIZATION

- EPA must designate at least 20 High-Priority chemicals and 20 Low-Priority chemicals by end of 2019
- Prioritization rule established process to designate a chemical as High or Low-Priority for further evaluation
- High-Priority chemicals immediately move to risk evaluation
- Low-Priority chemicals do not move to risk evaluation
- For each EPA-initiated risk evaluation completed, EPA must designate another High-Priority chemical to take its place
- By law, process must take between 9 and 12 months

## RISK EVALUATIONS

- For the first 10 chemical risk evaluations, EPA will be issuing "Problem Formulation" documents that further refine the "Scope" documents published on June 22, 2017
- Pursuant to the Risk Evaluation procedural rule, EPA will issue draft risk evaluations and take public comment before finalizing
- Final risk evaluations must be issued 3 years following initiation, or late Fall 2019 for the "first 10" chemicals

## SECTION 6 RULEMAKING ACTIVITIES

- Evaluating comment on proposed rules for three chemicals used in degreasing (TCE) and paint removing applications (MC and NMP)

## FEES RULEMAKING

- Propose and finalize rule; will help defray implementation costs

## TSCA ACTIVE/INACTIVE INVENTORY

- Reporting to begin shortly; EPA will use information to determine whether a chemical is active or inactive in commerce

## SECTION 4 TEST ORDERS

- Evaluate use of new authority to issue orders requiring development of information
- Strategic Plan for advancing use of non-animal testing approaches
- Deadline June 2018

## MERCURY REPORTING RULE

- Proposed rule expected late 2017 and final rule deadline 2018; will help inform future versions of the Mercury Inventory

## PBT CHEMICALS

- Expedited rulemaking to reduce exposures; required in section 6(h) of TSCA

## HOT ISSUES:

- New Chemicals – EPA commitment to clear "backlog" by end of July; public meeting in Fall 2017 on process/policy changes resulting from TSCA amendments
- Risk Evaluation Scoping – questions from public, press, and Congress on approach to "conditions of use"; evaluation of "legacy" uses; next steps for the First 10 risk evaluations
- Section 6 Rules – questions from public, press and Congress on status of proposed rules

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
|---|---|
| OCSPP/OPPT | ORD, OLEM, OW, OECA, OCHP, R5, OP, OGC |

# ACTIVE/INACTIVE INVENTORY RULE

## ISSUE/TOPIC:

Final "framework" rule requiring reporting by chemical manufacturers to help determine which chemicals on the TSCA Inventory are still actively manufactured or processed.

## BACKGROUND:

- There are over 85,000 chemical substances listed on the TSCA Inventory.
- It is probable that only a subset of those chemicals are still actively manufactured or processed.
- The Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, requires EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either "active" or "inactive" in U.S. commerce.
- To accomplish that, EPA finalized a rule requiring industry reporting of chemicals manufactured (including imported) or processed in the U.S. over the past 10 years, ending on June 21, 2016.
- Reporting will be used to identify which chemical substances on the TSCA Inventory are active in U.S. commerce and will help inform the prioritization of chemicals for risk evaluation.
- Additionally, active and inactive designations for each chemical substance will be included as part of the Agency's regular publications of the TSCA Inventory.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- ✓ Final rule signed on June 22, 2017
- ✓ Reporting under the final rule is expected to begin in August
- ✓ Compared to the proposal, the final rule eases reporting burdens

## HOT ISSUES:

N/A

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
|---|---|
| OCSPP/OPPT | OGC |

# PRIORITIZATION RULE

## ISSUE/TOPIC:

Procedural "framework" rule for prioritizing chemical substances for risk evaluation.

## BACKGROUND:

- TSCA required EPA to establish, by rule, the process and criteria for prioritizing chemical substances for risk evaluation. See TSCA section 6(b)(1)
- High-Priority substances move immediately to risk evaluation, whereas substances designated as Low-Priority do not receive further evaluation at the time.
- TSCA provided some specificity on both the process and criteria, including preferences for certain chemical substances that EPA must apply, the procedural steps, definitions of High-Priority Substances and Low-Priority Substances, and screening criteria that EPA must consider in designating a chemical substance as either High-Priority Substances or Low-Priority Substances.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

### SUMMARY OF PRIORITIZATION PROCESS:

✓ Final Rule Published on June 22, 2017

1. Initiation. Announcement of candidate chemical, followed by 90-day public comment
2. Proposed Designation. Based on screening review, proposed as either High- or Low-Priority, followed by 90-day public comment
3. Final Designation. Chemical finalized as either High- or Low-Priority Substance, with High-Priority substances immediately moving to risk evaluation.

***By law, process must take between 9-12 months from Initiation to Final Designation

## HOT ISSUES:

### "PRE-PRIORITIZATION":

EPA initially proposed a phase for information gathering and identification of potential candidates that would occur *prior to* the official start of prioritization, but deferred final action on this regulatory provision based on public comments. Additional stakeholder meetings planned for Fall 2017.

## LEAD OFFICE/REGION:

OCSPP/OPPT

## OTHER KEY OFFICES/REGIONS:

ORD, OLEM, OW, OECA, OCHP, R5, OP, OGC

# RISK EVALUATION RULE

## ISSUE/TOPIC:

Under TSCA section 6(b)(4), EPA was required to issue a rule to establish a process for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use.

## BACKGROUND:

- The final rule was published on June 22, 2017, meeting the statutory 1-year deadline.
- The proposed rule was published on January 19, 2017, followed by a 60-day public comment period.
- This process incorporates the science requirements of the amended statute, including best available science and weight of the scientific evidence.
- Risk evaluation is the second step, after Prioritization, in a new process of existing chemical substance review and management established under recent amendments to TSCA.
- This rule identifies the steps of a risk evaluation process including: scope, hazard assessment, exposure assessment, risk characterization, and finally a risk determination.
- Chemical substances designated as High-Priority Substances during the prioritization process and those chemical substances for which EPA has initiated a risk evaluation in response to a manufacturer request, will always be subject to this process.
- The final rule also includes the required "form and criteria" applicable to such manufacturer requests.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- To the extent practicable, this process will be used for the first ten chemical substances undergoing evaluation

## HOT ISSUES:

- The changes made from the proposed rule (January, 19, 2017) to the final rule have drawn a mixed response and Congressional interest.
- Senator Udall has publically commented on this rule, expressing concern that the rule preferentially benefits industry at the expense of public safety.
- Representative Pallone has expressed interest in seeing the changes from the proposed to the final rule.
- The major points of contention of this rule are:
  - The Agency's implementation of the statutory requirement to evaluate the chemical under the 'conditions of use'. The Agency proposed the consideration of 'all' conditions of use, while the final rule provides more discretion to evaluate the riskiest uses.
  - The codification of definitions for 'weight of scientific evidence' and 'best available science,' which were not defined in the proposed rule. Many environmental NGOs feel strongly these terms should not be defined in the rule, as they are not statutorily defined and will tie the hands of the Agency in the future.
  - The form and manner by which manufacturers can request a chemical they manufacture undergo risk evaluation. In the proposed rule the requestor had to submit all the information for all conditions of use, and in the final rule they are able to submit just the information for the use(s) of interest.

## LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

# TSCA FEE RULES

## ISSUE/TOPIC:

Collection of fees from chemical manufacturers and processors, as authorized under the 2016 amendments to TSCA

## BACKGROUND:

- The 2016 amendments to TSCA significantly increased EPA's authority to collect fees from chemical manufacturers and processors, and once established, will defray some of the costs of implementing the Agency's new responsibilities under the law.
- Prior to the amendments, the Agency had authority to require, by rule, the payment of fees by persons required to submit data under TSCA sections 4 and 5. Although authorized under the statue, the Agency has not collected fees for data submitted under TSCA section 4 and no TSCA section 4 rule was ever promulgated by the EPA. Section 5 fees were capped by statute at $2,500 per submission ($100 for small businesses). Since 1988, fees collected under TSCA have gone to the U.S. Treasury General Fund, and have not directly supported TSCA implementation.
- The EPA will now be able to collect user fees from chemical manufacturers and processors to defray 25 percent of its costs for administering Sections 4, 5, 6 and 14 of TSCA as amended, or up to $25 million a year for the first three years, whichever is less. Fees collected will now be deposited into a new "TSCA Service Fee Fund" which will directly support implementation activities.
- The EPA intends to propose increased fees for PMN review and to add fee categories for activities conducted under TSCA sections 4 (*e.g.*, test rules, test orders and enforceable consent agreements) and 6 (*e.g.*, risk evaluations).
- Before collecting new fees to supplement appropriations and help pay for implementation of the amended law, the EPA must develop a final rule governing the collection and administration of those fees.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- ✓ The EPA engaged with members of the public potentially subject to the fees on the following: public meeting and webinar held on August 11, 2016; industry-specific consultation meeting and webinar held on September 13, 2016; and dockets opened to collect written comments from stakeholders.
- ✓ A draft of the proposed TSCA User Fee Rule is currently under development.

## HOT ISSUES:

- Manufacturer-requested risk evaluations will not be accepted until the Fees Rule has been finalized.
- Reduced fees for small businesses.
- The FY 2018 President's Budget anticipated fee collections would begin in Q2 of FY 2018 and shifts $8.6M and 53.6 FTE from annual CRRR appropriations to new TSCA fee collections.

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
|---|---|
| OCSPP/OPPT | OCFO, OGC, OP, ORD, OLEM, OW, OCHP |

# FIRST 10 CHEMICAL RISK EVALUATIONS

## SUMMARY:

As required under section 6(b)(4) of the Toxic Substances Control Act (TSCA) as recently revised, EPA must conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use. TSCA instructs the Agency to identify the first 10 chemicals to undergo risk evaluation from the 2014 TSCA Work Plan, initiating a pipeline of chemical risk evaluations subject to statutory deadlines, minimum throughput and re-population requirements.

## BACKGROUND:

- The first 10 chemicals to undergo risk evaluation were announced in December 2016:

| | |
|---|---|
| 1,4-Dioxane | Methylene Chloride |
| 1-Bromopropane | N-methylpyrrolidone (NMP) |
| Asbestos | Pigment Violet 29 |
| Carbon Tetrachloride | Trichloroethylene (TCE) |
| Cyclic Aliphatic Bromide Cluster (HBCD) | Tetrachloroethylene (PERC) |

- These chemicals were drawn from EPA's 2014 TSCA Work Plan, a list of 90 chemicals selected based on their potential for high hazard and exposure as well as other considerations.
- Announcement of the first 10 chemicals triggered a statutory deadline to complete risk evaluation for these chemicals within three years.
- Under the newly amended law, EPA was required to release a scoping document within six months for each chemical. This includes the hazard(s), exposure(s), conditions of use, and the potentially exposed or susceptible subpopulation(s) the agency plans to consider for the evaluation.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- On June 22, 2017 and meeting the statutory deadline, EPA published the scopes of these first 10 chemicals, which include hazards, exposure, conditions of use, and potentially exposed or susceptible subpopulations considered in the risk evaluation.
- Because there was insufficient time for EPA to provide an opportunity for public comment on a draft the scope documents, EPA will publish and take public comment problem formulation documents.
- The problem formulation documents will refine the current scopes, and are expected to be published in December 2017-January 2018.

## HOT ISSUES:

- EPA's decision to not include legacy uses as a 'condition of use' that will be evaluated in the risk evaluations, has received some negative attention, particularly for asbestos. This would include, for example, types of products that contain asbestos that are no longer being manufactured, but may be in a person's home.

## LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

# GUIDANCE TO ASSIST INTERESTED PERSONS IN DEVELOPING RISK EVALUATIONS

## SUMMARY:

Within the first year after amended TSCA was signed into law, EPA was required to develop guidance to assist interested persons in submitting draft risk evaluations on chemical substances to be considered by the Agency.

## BACKGROUND:

- In accordance with TSCA section 26(l)(5), no later than one year after the date of enactment, EPA shall develop guidance to assist interested persons in developing and submitting draft risk evaluations that shall be considered by the Agency.
- The guidance addresses the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration.
- The process covered in this guidance addresses the minimum components of a risk evaluation as enumerated in TSCA section 6(b), as well as the process codified in the Risk Evaluation Rule.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- The 'Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluation Under the Toxic Substances Control Act' was released on June 22, 2017, meeting the statutory deadline.
- The Agency is uncertain at this time of the public interest in this provision, and has not yet received any submitted draft risk evaluations.
- EPA welcomes and will review and consider submitted draft risk evaluations, and in general they will be treated as additional information to information Agency actions or decision making.

## HOT ISSUES:

- EPA did not provide an opportunity for a formal public comment on this document, but did open a docket to accept any comment or questions.
- EPA will consider updating this document in the future as the Agency and public become more familiar with the risk evaluation process.

## LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

# PERSISTENT, BIOACCUMULATIVE AND TOXIC (PBT) CHEMICALS – EXPEDITED RULE MAKING

## SUMMARY:

Certain persistent, bioaccumulative, and toxic (PBT) chemicals have been specifically identified as a priority for action under TSCA section 6(h), which requires EPA to take expedited regulatory action to address risks from such chemicals.

## BACKGROUND:

- TSCA section 6(h) requires EPA to take expedited regulatory action under section 6(a) for certain PBT chemicals from the 2014 update of the TSCA Work Plan for Chemical Assessments without a risk evaluation, and to meet a statutory deadline of June 2019 for a proposed rule, with a final rule to follow no more than 18 months later. EPA does need to consider exposure. This directive is separate from the process outlined in the statute for the initial ten chemicals selected for risk evaluation.
- As a first step in the TSCA section 6(h) process, five PBT chemicals were identified for action in keeping with the statutory criteria
    - Decabromodiphenyl ethers (DecaBDE), used as a flame retardant in textiles, plastics, wiring insulation, and building and construction materials;
    - Hexachlorobutadiene (HCBD), used as a solvent in the manufacture of rubber compounds and as hydraulic, heat transfer or transformer fluid;
    - Pentachlorothiophenol (PCTP), used as a mercaptan (sulfur) cross-linking agent to make rubber more pliable in industrial uses;
    - Phenol, isopropylated, phosphate (3:1), used as a flame retardant in consumer products and as lubricant, hydraulic fluid, and other industrial uses; and
    - 2,4,6-Tris(tert-butyl) phenol, an antioxidant that can be used as a fuel, oil, gasoline or lubricant additive.
- Two additional PBT chemicals met the TSCA section 6(h) criteria; however, manufacturers for these substances submitted timely requests to EPA for risk evaluations pursuant to section 6(h)(5) and are therefore not subject to the rulemaking effort. As a result of the requests, Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl) and Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl are excluded from the expedited action requirements under TSCA section 6(h).

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

EPA has established public dockets for each of the five PBT chemicals to facilitate receipt of information on exposure and use which may be useful to the Agency's rulemaking effort. EPA is requesting that any information be submitted to the docket by December 2017 so that the information can inform any regulatory action.

## HOT ISSUES:

To date, this rulemaking has not received significant public attention, though manufacturers of these chemicals have initiated discussions with EPA. Issues expected to be addressed in the near future include

identifying the conditions of use for each of the chemicals and exposures to the general population, potentially exposed or susceptible subpopulations, and the environment.

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
|---|---|
| OCSPP/OPPT, with a cross-agency workgroup formed as part of the rulemaking process (including OLEM, ORD, OECA, OGC, and OP). | |

# NEW CHEMICAL REVIEWS

## ISSUE/TOPIC:

The 2016 TSCA amendments resulted in changes to EPA's new chemicals program. TSCA section 5 now requires EPA to review a new chemical (or significant new use of an existing chemical) and make affirmative determinations relating to safety of chemicals before those chemicals can proceed to market.

## BACKGROUND:

- The EPA typically receives approximately 1,000 new chemicals submissions per year and, by law, must conclude review of each submission within 90 days.
- EPA has approximately 300-350 cases under review at any given time.
- The amendments to TSCA, including the new affirmative determination mandate for new chemicals, went into effect immediately on June 22, 2016. New chemical submissions that were in the "queue" on that date were also subject to the new requirement.
- As a result of these changes, and given the need for EPA to revise processes to respond to the new requirements of TSCA, the throughput rate on determinations temporarily slowed and the number of cases undergoing review roughly doubled. This has been referred to as the new chemicals "backlog."

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

✓ EPA has worked to adjust its review process to meet the new requirements in TSCA, and has significantly reduced the backlog from roughly 350 to 100 cases. OCSPP remains committed to eliminating the backlog entirely, and continuing to improve the efficiency and effectiveness of its new chemicals program. OCSPP has already instituted a number of program changes, including increased staffing and process/policy changes.

## HOT ISSUES:

- Congressional Inquiries. Members in both the Senate Environment and Public Works Committee and the House Energy and Commerce Committee continue to express interest in EPA's efforts to eliminate the new chemicals "backlog." OCSPP has responded to a number of requests for information and briefings on this topic.
- Chemical manufacturers have raised concern about delays in bring new chemistries to market.

## LEAD OFFICE/REGION:

OCSPP/OPPT

## OTHER KEY OFFICES/REGIONS:

OGC

# TSCA CONFIDENTIAL BUSINESS INFORMATION (CBI)

## SUMMARY:

Section 14(a) of the Toxic Substances Control Act (TSCA) provides that submitters may claim information submitted to EPA under TSCA as confidential business information (CBI). EPA is working to implement significant changes to TSCA section 14 made by the Frank R. Lautenberg Chemical Safety for the 21St Century Act.

## BACKGROUND:

The Frank R. Lautenberg Chemical Safety for the 21St Century Act introduced new requirements relating to the submission of CBI, its management, and periodic reviews of CBI claims, including expiration of CBI claims.

All CBI claims must be substantiated at the time the information claimed as CBI is submitted to EPA, except for those types of information exempt under TSCA section 14(c)(2). The law requires that the submitter provide a statement concerning the need for the CBI claim and a certification that the statement of need is true and correct. EPA has collapsed the two requirements into a single certification statement. There is also a requirement that when a chemical identity is claimed as CBI, a non-CBI structurally descriptive generic name be provided.

EPA must, with limited exceptions, review all CBI claims for chemical identity, as well as a representative sample of at least 25% of other claims within 90 days of receipt. Other CBI claims may also be reviewed by the Agency based on specific events, such as pursuant to a Freedom of Information Act (FOIA) request, when a substance is designated as a high priority or active substance, or when the Agency believes that disclosure would be important in implementation of TSCA section 6. Most CBI claims expire after 10 years unless the information submitter reasserts and re-substantiates the CBI claim. When EPA approves a CBI claim for chemical identity, the Agency must develop a unique identifier for the chemical and apply the unique identifier to all information relevant to the applicable chemical substance. TSCA CBI may also be shared with non-federal authorities including states, subdivisions of states, tribes, emergency responders, and health care professionals if, certain requirements are met.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- January 19, 2017, Federal Register Notice announcing interpretation of statute as requiring substantiation of TSCA CBI claims at the time the information is submitted to EPA.
- May 8, 2017, Federal Register Notice requesting comment on the Assignment and Application of the "Unique Identifier" Under TSCA Section 14 and Public Meeting held on May 24, 2017.

## HOT ISSUES:

OPPT is expecting to announce its approach for implementing a unique identifier approach by the end of September.

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
| --- | --- |
| OCSPP/OPPT | OGC |

# ALTERNATIVE TESTING STRATEGIC PLAN

## SUMMARY:

The 2016 amendments to TSCA require the Administrator to "…reduce and replace, to the extent practicable, scientifically justified and consistent with the policies of this title, the use of vertebrate animals in the testing of chemical substances or mixtures…" (TSCA §4(h)(1))

## BACKGROUND:

- Section 4 of TSCA authorizes and provides specific requirements related to testing chemical substances and mixtures
- Subsection (h) is an amendment to TSCA provided in the Lautenberg Chemical Safety Act; it did not exist in original TSCA
- Agency requests for testing (and voluntary testing by stakeholders) must encourage and facilitate methods and approaches to reduce/replace the use of vertebrate animals
- Section 4(h)(2)(A) requires the Administrator to "…develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing and provide information of equivalent or better scientific quality…"
- This plan must be published by June 22, 2018, and not later than June 22, 2021 and every five years thereafter EPA must report to congress on progress implementing the plan and goals for future implementation

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- OPPT is on track to publish the initial Strategic Plan by June of 2018
- February: OPPT began more active participation in the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM, a permanent committee of the National Institute of Environmental Health Sciences [NIEHS] established by law in 2000. It is composed of representatives from 16 U.S. federal agencies and is charged with establishing, where feasible, "…guidelines, recommendations, and regulations that promote the regulatory acceptance of new or revised…tests…while reducing, refining or replacing animal tests…")
- March: OPPT conducted outreach to scientific community by providing an overview of the new requirements to the Annual Society of Toxicology (SOT) meeting
- April: OPPT began substantive intra-agency discussions with EPA offices with equities and expertise to contribute to the strategy, e.g., OCSPP's Office of Pesticide Programs and Endocrine Disruptor Program and ORD's National Center for Computational Toxicology; all of which have developed and/or tested use of alternative test methods in the context of conducting risk assessment
- May: OPPT conducted outreach to the international chemical's management community by providing an overview of new requirements to the Organization for Economic Cooperation and Development's Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology; follow-up conference call with parties (25 lines were open, multiple government authorities from various countries and some stakeholders; participant list not yet circulated) with past experience and interest in collaboration in July
- June: conducted outreach to the scientific community by presenting progress to date to the Society of Toxicology's Specialty Section on In Vitro Methods

- July-September: working on developing a substantive outline for a stakeholder workshop to be held in November

## HOT ISSUES:

There has been some attention by certain non-governmental organizations (NGOs) and industry stakeholders on this topic/project. OPPT is getting inquiries by stakeholders (in and outside the agency) as interested parties become more aware of this section of the amended TSCA and as the June 2018 deadline draws near.

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
|---|---|
| OCSPP/OPPT<br>ORD/NCCT | OCSPP/OPP; OCSPP/OSCP-EDSP; |

# MERCURY

## SUMMARY:

OCSPP addresses environmental release and exposure to mercury by working to reduce its use in favor of safer alternatives.

## BACKGROUND:

- Mercury is an element found in the earth's crust
- In the environment, mercury is a persistent, bioaccumulative neurotoxicant
- People can be exposed to mercury from both natural and man-made sources, including volcanic release, burning of coal, and use in products and processes
- Although mercury use has declined substantially, it continues despite the availability of cost-effective substitutes for some uses
- Responsibility for implementing a federal ban on export of mercury lies with OCSPP

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

As required by the 2016 amendment to the Toxic Substances Control Act (TSCA), OCSPP has met two statutory deadlines:

1. published a notification of the mercury compound export ban in the Federal Register on August 26, 2016,
2. published the initial mercury inventory (based on publicly available information) in the Federal Register on March 29, 2017.

To implement another provision in the 2016 amendment to TSCA, OCSPP is developing a triennial inventory of supply, use, and trade. The law directs EPA to promulgate a regulation to collect information from manufacturers to assist in preparing the inventory. Three groups of manufacturers are identified for reporting: mercury manufacturers, manufacturers of mercury-added products, and manufacturers who otherwise intentionally use mercury.

In carrying out the inventory, EPA must identify any manufacturing process or product and recommend actions including regulations to achieve reduction in mercury use. The final rule deadline is June 22, 2018, and OCSPP is currently developing the proposed rule for publication and comment.

## HOT ISSUES:

Congressional interest in mercury is reflected in provisions of the 2016 amendment to the Toxic Substances Control Act (TSCA) that OCSPP implements as described above.

## LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

# TOXICS RELEASE INVENTORY (TRI)

## SUMMARY:

The Toxics Release Inventory (TRI) is an information disclosure program covering toxic chemical releases and other waste management (e.g., recycling) quantities by industrial facilities. The TRI program was established by section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 and later expanded by section 6607 of the Pollution Prevention Act (PPA) of 1990.

## BACKGROUND:

- By July 1 of each year, more than 20,000 facilities across the United States in the manufacturing, electricity generation (oil and/or coal-fired), mining, solvent recovery, and other sectors, report electronically to EPA's TRI Program each facility's prior calendar year releases, other waste management (recycling, energy recovery, treatment) quantities, and source reduction on more than 650 TRI-listed toxic chemicals.
- EPCRA requires the manufacturing sectors to report to TRI. In a 1997 final rule, the Agency added seven additional sectors to TRI, including mining and electricity generation.
- The Agency receives more than 80,000 TRI reports each year from the 20,000+ facilities reporting to TRI.
- Pursuant to the statute, the EPA makes the TRI data publicly accessible; first publishing, in user-friendly electronic formats, the Preliminary TRI Data in July, within three weeks of the July 1 submission deadline and then publishing an updated, "frozen" National Analysis dataset, in the fall. This latter dataset is the snapshot of TRI reporting that is used by EPA to develop the annual TRI National Analysis, which is the Agency's interpretation of the TRI data as evaluated by trends and "data cuts" focused on specific chemicals, sectors, parent company, and other variables. The TRI National Analysis is published as an interactive website in January of each year.
- The TRI data is used by a wide range of internal and external stakeholders including government (including EPA program offices), academia, industry, community organizations, the media, concerned citizens, and the financial community, to assist with research, policy decisions, informed dialogue, and many other uses.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- In October 2016, the TRI marked its 30th anniversary as the Agency's premier, multi-media right-to-know program.
- In January 2017, the TRI Program published the TRI National Analysis for the 2015 TRI dataset. The National Analysis showed that total TRI-reported releases decreased by 15% and total TRI-reported waste decreased by 3% between 2014 and 2015.
- On July 19, 2017, the Agency published the 2016 calendar year Preliminary Data submitted by industry to EPA by July 1, 2017.
- The TRI continues to serve as an invaluable data source for TSCA implementation and TSCA and other priority chemicals are being considered for inclusion on the TRI Chemical List.

## HOT ISSUES:

- As part of the Agency's Regulatory Reform docket, comments from the National Mining Association (NMA), other mining associations, and specific mining companies have requested regulatory relief from the TRI reporting requirements, either in full or at least with regard to naturally occurring chemicals mined from the earth. OCSPP is currently evaluating these comments and considering options for burden relief and for additional ways to place mining data reported to TRI in context to avoid misuse or misunderstandings of the TRI data.
- The Agency has placed the Proposed Rule to Add Natural Gas Processing (NGP) Facilities to TRI on the 2017 Inactive Actions List of the Regulatory Agenda.

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
|---|---|
| OCSPP/OPPT | OEI |

While the TRI Program is located in OCSPP, the TRI Information Technology (IT) systems and tools are managed by the Office of Environmental Information (OEI). Each Region has a Regional TRI Coordinator.

# SAFER CHOICE PROGRAM

## SUMMARY:

Safer Choice is a voluntary, stakeholder-driven program designed to recognize and partner with industry by developing products and chemicals that benefit people and the environment; the Safer Chemical Ingredients List (SCIL) includes chemicals used in Safer Choice-labeled products.

## BACKGROUND:

**Safer Choice Program** [ HYPERLINK "http://www.epa.gov/saferchoice" ]

- Formerly the Design for the Environment (DfE) Program, redesigned to Safer Choice in 2015
- Developed with a broad cross-section of stakeholders
- Allows use of the Safer Choice label on cleaning and other products that meet human health and environmental criteria
- About 2,000 products from 500 American manufacturing partners
    - Many Safer Choice partner companies are small businesses
- Program participants include:
    - Chemical manufacturers (e.g., AkzoNobel, BASF, Dow, Eastman, Milliken, Novozymes, Stepan)
    - Product manufacturers
        - Large companies: BISSELL, Clorox, Church & Dwight, Ecolab, GOJO, Proctor & Gamble, RB, WD-40, others
        - Small businesses: Berkley Green, Clean Control, Earth Friendly Products, Honest Company, Jelmar (CLR), Seventh Generation, State Industrial, Sun Products, Wexford Labs, others
    - Retailers (e.g., Albertsons/Safeway, Amazon, Brandless, Costco, Home Depot, Office Depot/Office Max, Sears, Staples, Target, Walmart, Wegmans)

**Safer Chemical Ingredients List (SCIL)** [ HYPERLINK "http://www.epa.gov/saferchoice/safer-ingredients" ]

- Created to meet stakeholder demand for a list of chemicals that meet Safer Choice criteria for use in Safer Choice labeled products
    - Chemical manufacturers can identify and target opportunities for chemical innovation
    - Product manufacturers can select chemicals
- SCIL highlights green chemistry innovations by the chemical industry
- SCIL is a living list of 870 chemicals that meet Safer Choice's Criteria for Safer Chemical Ingredients
    - Chemicals are organized by functional-use categories (e.g., solvents, surfactants, chelants)

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

**Safer Choice label**

- 33 companies and organizations named 2017 Safer Choice Partners of the Year
- EPA supported online survey of 2,000+ adult U.S. residents in February 2016:
  - 35% say they have seen the Safer Choice label in stores
  - 76% of consumers–83% of parents and 86% of millennials–responded that they would use the Safer Choice label to inform purchasing decisions
- 320 partnership products added or renewed in FY17

**Safer Choice Summit**

- Almost 200 company and organization attendees provided input for program enhancement

**Safer Chemical Ingredients List (SCIL)**

- 48 chemicals added to date in FY17

## HOT ISSUES:

- The SCIL may provide a source of candidate Low Priority Substances under TSCA
- Support for the 'safer" chemicals label is mixed throughout the stakeholder community

## LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

# NANOTECHNOLOGY

## SUMMARY:

Nanotechnology is the understanding and control of matter at dimensions of roughly 1-100 nanometers

## BACKGROUND:

- Many nanoscale materials are regarded as "chemical substances" under the Toxic Substances Control Act.
- Chemical substances that have structures with dimensions at the nanoscale -- approximately 1-100 nanometers (nm) -- are commonly referred to as nanoscale materials or nanomaterials
- EPA is moving expeditiously ensuring appropriate oversight of nanotechnology, while not unduly impeding its development.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

Since 2005, EPA has received and reviewed over 190 new chemical notices under TSCA for nanoscale materials.

EPA has approved nearly all of them for commercialization, in most cases allowing the manufacture of new chemical nanoscale materials under the terms of certain regulatory exemptions, but only in circumstances where exposures were tightly controlled to protect against unreasonable risks (using, for example, the exposure and environmental release limitations discussed above).

On January 12, 2017, as part of the Agency's effort to ensure a more comprehensive understanding of nanoscale materials in commerce, EPA issued a final regulation requiring one-time reporting and recordkeeping of existing exposure and health and safety information on nanoscale materials produced from substances already on the TSCA Inventory.

On May 12, 2017, EPA extended the effective date of the rule to August 14, 2017.
On May 15, 2017, EPA issued draft guidance for the rule asking for additional public comment. EPA will finalize its guidance by the August 14 effective date.

## HOT ISSUES:

Concerns about the reporting rule were raised in public comment on the regulatory reform activity.

## LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

# POLLUTION PREVENTION (P2) PROGRAM

## SUMMARY:

The EPA's Pollution Prevention (P2) Program complements EPA's regulatory programs by working with businesses, states, and other partners to encourage and facilitate adoption of source reduction approaches through: (a) the development and delivery of P2 information and tools; (b) technical assistance; (c) the funding and facilitation of P2 innovations; and (d) the sharing and amplification of those innovations so that others can replicate approaches and outcomes.

## BACKGROUND:

Pollution prevention (P2), also called "source reduction," is any practice that reduces, eliminates, or prevents pollution at its source. The EPA P2 Program:

- Provides P2 Information, Training and Technical Assistance to Businesses: As required by the P2 Act of 1990, EPA makes **grants** available to **states and tribes** to promote adoption of pollution prevention by businesses. These grants fund outreach efforts by states and tribes to provide direct P2 technical assistance and training for businesses, aid in development and adoption of P2 solutions and innovations, and sharing those innovations across state and regional boundaries so that others can benefit from and replicate P2 approaches and outcomes.

- Supports Markets with Information:
  - The EPA **Environmentally Preferable Purchasing (EPP) Program** maintains Recommendations of Specifications, Standards, and Ecolabels in order to provide clear information to federal procurement officials -- and manufacturers and service providers -- about which of the many private sector standards and ecolabels demonstrate effective environmental performance of products and service. This work also supports the P2 Act requirement that EPA identify opportunities to use Federal procurement to encourage pollution prevention.
  - The EPP Program also works with a variety of non-governmental standards development organizations to promote development of voluntary consensus standards for environmentally preferable goods and services.

- The Presidential Green Chemistry Challenge Awards: A recognition program for innovative, green chemistry technologies.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

P2 Technical Assistance and Information for Business: Between 2011-2015, the EPA's P2 program issued 281 assistance grants for $31.6 million, which resulted in four-year rolling benefits estimated at:

- $1.1 billion in savings
- 401 million pounds of hazardous materials reduced
- 23.6 billion gallons of water saved
- 10.8 million tons of greenhouse gases eliminated

- 15.38 billion kilowatt hours of energy savings

Supporting Markets with Information (EPP): In September 2015, in accordance with Executive Order 13693 and the OMB implementing instructions, EPA, in consultation with OMB and the White House Council on Environmental Quality (CEQ), issued interim recommendations for standards and ecolabels for federal procurement. In December 2016, EPA completed a pilot using multi-stakeholder developed Guidelines to assess approximately 50 standards and ecolabels from 20 organizations from the furniture, flooring and paints/coatings product sectors. The EPA recommendations for these product categories were updated based on the results of this pilot.

Green Chemistry: During the 22 years of the Green Chemistry Challenge Awards program (through 2017), in partnership with the American Chemical Society, the EPA has received more than 1,700 nominations from American innovators and presented awards to 114 technologies.

## HOT ISSUES:

P2: Has been proposed for elimination under the FY 18 President's Budget.

EPP: Based on stakeholder concerns and interagency discussions, the EPA recommendation for the lumber/wood product category was removed in December 2016 and put on hold. Before further action on this product category, EPA would continue coordination with the USDA Forest Service and USDA Natural Resources Conservation Service, Department of Energy, OMB, and CEQ to determine how forestry standards should best be evaluated. The Fiscal Year 2018 President's Budget eliminates all staff and contract funding for this program. Therefore, further action on the lumber/wood category is uncertain.

## LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

# FORMALDEHYDE

## SUMMARY:

- The Formaldehyde Standards for Composite Wood Products Act (TSCA Title VI) required that EPA promulgate a rule to set formaldehyde emission standards for composite wood products and implement provisions to ensure compliance with those standards. EPA published a final rule on December 12, 2016. The Agency has since promulgated proposed rule amendments to address issues that have arisen with compliance dates and the labeling of composite wood products since the December 12, 2016 final rule.

## BACKGROUND:

***Formaldehyde Background***

- Formaldehyde is a colorless, flammable gas at room temperature and has a strong odor.
- Formaldehyde can cause respiratory irritation, watery eyes and is classified by EPA as a probable human carcinogen.
- Travel trailers used after Hurricanes' Katrina and Rita in 2005 contained composite wood that emitted high levels of formaldehyde, bringing national attention to the issue.
- The California Air Resources Board (CARB) established a Formaldehyde Air Toxics Control Measure (ATCM) in 2007.
- On March 24, 2008, Sierra Club, et al. submitted a TSCA Section 21 petition requesting EPA adopt the CARB standards through section TSCA 6(a).
- EPA partially denied and accepted the petition to investigate potential regulatory action.
- OPPT held meetings nationwide to take comment on potential EPA action.
- Industry and environmental groups then worked with Congress to craft the Formaldehyde Standards for Composite Wood Products Act, which added Title VI to the Toxic Substances Control Act (TSCA) in 2010.

***The Formaldehyde Standards for Composite Wood Products (TSCA Title VI)***

- On July 27, 2016, EPA finalized a rule to implement TSCA Title VI.
- The purpose of the law is to reduce formaldehyde emissions from composite wood products, which will reduce overall exposures to formaldehyde and result in benefits from avoided adverse health effects.
- The statute established the same formaldehyde emission standards for composite wood products including hardwood plywood, medium-density fiberboard, and particleboard, as established by the CARB ATCM.
- Although the emission standards are the same under CARB, the statute directed EPA to address areas not included in CARB's standards.
    - Congress deferred to EPA to determine whether laminated products should be considered "hardwood plywood" after considering available information and ensuring compliance with the emission standards.

***Final Rule Implementing TSCA Title VI***

- Rule issued on December 12, 2016.
- Under the rule, composite wood products need to be tested, certified, labeled and records kept as compliant beginning on December 12, 2017.

- The rule also establishes a third-party certification program and includes procedures for the accreditation bodies (ABs) and third-party certifiers (TPCs).

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

***TSCA Title VI Rule Amendments Underway***

**Compliance Dates**

- The December 12, 2016, final rule effective date was extended from February 10, 2017 to May 22, 2017, to allow the new Administration time to review the rule provisions.
- EPA addressed this issue by promulgating a direct final rule and parallel proposal on May 24, 2017 to extend the compliance dates; however, negative comment was received so EPA has withdrawn the direct final rule and is now proceeding to issue a subsequent final rule on the compliance dates based on the comments received.

**Early Labeling**

- EPA has issued a direct final rule and parallel proposal to allow regulated composite wood products and finished goods that meet the formaldehyde emissions standards, and have been certified by an EPA-recognized TPC, to be voluntarily labeled as compliant as soon as compliance can be achieved before the emission standards, labeling, and recordkeeping compliance date.
  - Public comment period closed July 26, 2017.

**Voluntary Consensus Standards**

- EPA will also soon issue a direct final rule and parallel proposal to allow regulated entities to use most current versions of voluntary consensus standards incorporated by reference in the rule, consistent with CARB.
  - Rule is currently undergoing Office of Federal Register review for Incorporation by Reference of the new standards

## HOT ISSUES:

***Import Certification***

- Some industry stakeholders requested that EPA remove the TSCA import certification requirement.
  - Some industry stakeholders believe the TSCA import certification is unnecessary given that recordkeeping is required for importers to ensure imported composite wood product is TSCA Title VI compliant
  - Other industry stakeholders are supportive of the TSCA import certification requirement because they feel the provision further deters non-compliance of foreign-manufactured products by involving Customs and Border Patrol in monitoring imports.

***Laminated Products***

- Industry requested EPA exempt all laminated products from testing and certification requirements which kick in 7 years after promulgation.
- EPA concluded based on the data provided to the Agency not to exempt all laminated products in the final rule.
  - The public is able through the 12/12/16 final rule to petition EPA to exempt additional laminated products made with other resins/technology from the definition of hardwood plywood based on testing data showing compliance.

- A stakeholder dialogue/workshop is anticipated to gauge the progression of resin technology.

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
|---|---|
| OCSPP/OPPT | OGC/OECA/OP/ORD |

# LEAD

## SUMMARY:

Although lead exposure has declined dramatically in the past 40 years because of actions by EPA, other federal agencies, and states, some populations continue to experience high lead exposures, particularly those in poorer and older neighborhoods. EPA has statutory authorities for addressing lead exposure from air, soil, water, household dust, and old paint and works closely with other federal, state, and local partners to continue reducing lead exposure across the population and internationally.

## BACKGROUND:

403 Hazard Standards

- In 2001, EPA established lead hazard standards in dust and soil for residences and child-occupied facilities. EPA's Lead-based Paint (LBP) and Renovation, Repair and Painting (RRP) regulations ensure that all work done by abatement and renovation contractors is done safely and avoids leaving dust that exceeds these standards.
- In 2009, without specifying a timetable for completion, EPA granted a petition which requested that EPA lower the regulatory hazard standard for lead in dust on floors (40 µg/ft2) and window sills (250 µg/ft2).

Public and Commercial Buildings (P&CB)

- § 402(c)(3) of the Toxics Substances Control Act (TSCA) directs EPA to promulgate regulations for renovations in target housing, public buildings built before 1978 and commercial buildings that create lead-based paint hazards.
- For renovations that create lead-based paint hazards, TSCA directs EPA to promulgate work practice, training and certification requirements.
- In 2008, EPA promulgated final regulations applicable to renovations in target housing (pre-1978 residential dwellings) and child-occupied facilities (a subset of P&CBs). Shortly thereafter, a group of litigants challenged the 2008 RRP rule, in part for EPA's failure to evaluate lead-based paint hazards in P&CBs by the statutory deadline (April 1994). The EPA entered into a settlement agreement that, among other things, established a timeline for action on P&CB renovations unless a determination was made that these activities do not create lead-based paint hazards. The settlement has been renegotiated several times since the original agreement.

## HIGHLIGHTS:

403 Hazard Standards

- On August 24, 2016, several plaintiffs filed a petition seeking a court order compelling EPA to issue a proposed rule within 90 days of that order, and a final rule within six months. Petitioners contend that EPA has unreasonably delayed its commitment to initiate a rulemaking to lower the hazard standard for lead in dust.
- On January 17, 2017, EPA filed its brief and declaration; petitioner's response brief was filed on January 27, 2017; oral argument occurred June 12, 2017. EPA is waiting on a decision from the court.

Public and Commercial Buildings

- The litigants informed DOJ/OGC in December 2016 that they intend to reactivate the litigation instead of negotiating a new settlement deadline. No further discussions with litigants have occurred and EPA missed the March 31, 2017 deadline.

## HOT ISSUES:

- EPA's FY 18 budget virtually eliminates the Lead Hazard Reduction Program except for application processing and database management.

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
| --- | --- |
| OCSPP/OPPT<br>Regional offices | ORD, OGC, OCHP, OP, OECA, OLEM, OAR, |

# POLYCHLORINATED BIPHENYLS (PCBs)

## SUMMARY:

OCSPP manages the continued use of PCBs in buildings and electrical equipment in the U.S. pursuant to TSCA Section 6(e) and 40 CFR part 761.

## BACKGROUND:

***General PCB Background***

- PCBs belong to a broad family of man-made organic chemicals known as chlorinated hydrocarbons. PCBs were widely used due to their non-flammability, chemical stability, high boiling point and electrical insulating properties.
- PCBs can cause a variety of adverse health effects, including cancer and effects on the immune system, reproductive system, nervous system and endocrine system.
- PCBs were used in hundreds of industrial and commercial applications from 1929 until the manufacture, processing, distribution in commerce and use of PCBs was banned under Section 6(e) of TSCA in 1979.
- TSCA Section 6(e) provides that, if it can be demonstrated that there is no unreasonable risk of injury to health or the environment, then EPA may authorize continued uses of PCBs by regulation.
- PCBs are still authorized for use in certain applications including electrical equipment.
- The use of PCB building materials with greater than or equal to 50 ppm PCBs is banned unless specifically authorized by regulation. There is no requirement that building materials be tested for the presence of PCBs.
- OCSPP oversees the continued use of PCBs in buildings and equipment, while the Office of Land and Emergency Management (OLEM) oversees the disposal of PCBs.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

***PCBs in School Buildings***

***Fluorescent Light Ballasts in Schools Proposed Rulemaking***

- Schools built or renovated between 1950-1979 have widespread use of polychlorinated biphenyls (PCBs) containing building materials (e.g., non-liquid PCBs in caulk and paint, and liquid PCBs in fluorescent light ballasts (FLB)). EPA is aware of a number of incidents involving releases of PCBs from FLBs in schools that have occurred across the country including hundreds of incidents in New York City, Los Angeles and elsewhere.
- EPA sent a proposed rule to the Office of Management and Budget (OMB) in late 2016 to end the use authorization for PCB-containing fluorescent lights ballasts (FLB) in schools and daycare centers after December 31, 2020.
- EPA's proposal also included, as a condition of use of PCB FLBs until December 31, 2020, that school building and daycare administrators, including owners and operators, will have to notify building occupants, including parents or guardians of minors attending the facility, of the presence of any PCB FLBs. Note that, even in the absence of a new regulation, leaking PCB FLBs are not authorized and must be properly removed and disposed.
- The proposed rule was sent back from OMB to EPA in January 2017.

***PCBs in School Building Materials***

- The PCBs Building Materials Workgroup, led by OPPT, issued updated PCBs in Building Materials—Questions & Answers guidance, and associated Fact Sheet in July 2015 to provide guidance on addressing PCBs in school buildings.
- The PCBs Science Workgroup, led by the Office of Research and Development (ORD), developed Exposure Levels for Evaluating PCBs (ELEs) in indoor school air and on surfaces. The air ELEs are public on the EPA website while the surface ELEs are not. Both the air and surface ELEs will tentatively undergo external peer review in Fall 2017.
- EPA's Integrated Risk Information System (IRIS) program is in the early stages of developing a draft assessment for the non-cancer effects of PCBs. The draft assessment is expected to be ready for agency review in the third quarter of FY 2018.
- EPA is currently working to develop more consistency among the EPA regions in handling this issue.

## HOT ISSUES:

***PCBs in School Buildings***

- Some external, non-EPA cost estimates for schools to come into compliance nationwide with TSCA PCB requirements are in the billions of dollars, although the number of schools affected and the amount of material in schools is unknown.
- Advocacy groups alleged TSCA violations against Santa Monica-Malibu Unified School District. EPA was not a party to the lawsuit, but EPA Region 9 approved the school district's plan to address contaminated substrate and worked with the school district as they implemented best management practices and conducted comprehensive air and wipe sampling.

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
|---|---|
| OCSPP/OPPT/ | OLEM/OGC/ORD/Region 9 |

# PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS)

## SUMMARY:

Per- and polyfluoroalkyl substances (PFAS) are a large family of man-made chemicals that include perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), are persistent in the environment, and are distributed globally. PFAS chemicals—primarily PFOA and PFOS, but also others—have been used widely in consumer products, firefighting foams at air fields, and in industrial processes. PFAS chemicals have been detected at sites across the country, often in drinking water. There is substantial concern about the effects of PFAS on public health. EPA is working with federal partners, states, tribes, communities, and industry to address public concerns related to PFAS chemicals, including PFOS and PFOA.

## BACKGROUND:

- There is concern about the effects of PFAS on public health, including increased cholesterol levels, low infant birth weights, effects on the immune system, thyroid hormone disruption, and an increased risk for kidney and testicular cancer. There is also concern for the reproductive and life stage health risks of the more sensitive populations, including pregnant mothers and breast-fed infants, from short-term exposures.
- Studies by Centers for Disease Control and Prevention (CDC) have found PFOA and PFOS in the blood of nearly all the people they tested because PFAS chemicals have been used in many consumer products, bioaccumulate, and do not break down in the environment. CDC studies have shown, however, that the levels of PFOA and PFOS in blood have been decreasing since companies stopped producing these chemicals, but information on potential levels of other PFAS chemicals, which are being used as alternatives, is lacking.
- Certain PFAS chemicals, including PFOA and PFOS, are no longer manufactured in the U.S. as a result of voluntary phase-outs under EPA's 2010/2015 PFOA Stewardship Program. EPA remains concerned about the ongoing uses of PFOA and related chemicals that are still available in existing stocks or are being newly introduced by companies not participating in the PFOA Stewardship Program.
- In 2016, EPA established non-regulatory health advisories for PFOA and PFOS in drinking water of 70 parts per trillion (ppt). The health advisories identified the concentration of PFOA and PFOS in drinking water at or below which adverse health effects are not anticipated to occur over a lifetime of exposure.
- EPA Offices and Regions (and other federal agencies) are learning more about the toxicity of PFAS chemicals as well as developing and validating necessary analytical methods to better understand PFAS exposures in communities.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- EPA's New Chemicals program reviews alternatives for PFOA and related chemicals before they enter the marketplace to identify whether the range of toxicity, fate and bioaccumulation issues that have caused past concerns with perfluorinated substances may be present in order to ensure that the new chemicals may not present an unreasonable risk to health or the environment.

- EPA has taken a range of regulatory actions to address PFAS substances in manufacturing and consumer products:
    - On January 21, 2015, EPA proposed a Significant New Use Rule (SNUR) that requires manufacturers (including importers) and processors of PFAS chemicals, including as part of articles, to notify EPA at least 90 days before starting or resuming new uses of the chemicals in any products.
    - On September 30, 2013, EPA issued a rule requiring companies to report all new uses of certain PFOA-related chemicals as part of carpets, a category of potentially harmful chemicals once used on carpets to impart soil, water, and stain resistance. Companies must now report to EPA their intent to manufacture (including import) these chemical substances intended for use as part of carpets or to treat carpets, as well as import carpets already containing these chemical substances.
- In 2006, EPA, in cooperation with eight major leading companies in PFAS industry, launched the 2010/2015 PFOA Stewardship Program with the goal of eliminating these chemicals from emissions and products by 2015. All participating companies have met the PFOA Stewardship Program goals EPA remains concerned about the ongoing uses of PFOA and related chemicals that are still available in existing stocks or are being newly introduced by companies not participating in the PFOA Stewardship Program.

## HOT ISSUES:

- There are geographical hotspots where exposures are higher than in the general population (e.g. Parkersburg, WV; Decatur, AL; Hoosick Falls, NY), and there are a growing number of investigations nationwide.
- Most recently, the N.C. Department of Environmental Quality (DEQ), in consultation with the N.C. Department of Health and Human Services (DHHS), is leading a state investigation into reports of an unregulated chemical known as GenX (replacing PFOA) in the lower Cape Fear River in N.C.
    - EPA is investigating Chemours' compliance with the requirements of a 2009 Consent Order issued under TSCA section 5 requiring control of releases to the environment associated with production of GenX at the company's Fayetteville, N.C., facility and potential impacts to Wilmington drinking water. EPA is also reviewing the additional toxicity data submitted by the company, as required under the Consent Order, and is updating the risk assessment using more recent production data and the additional GenX toxicity data.
    - Chemours, the company that produces the chemical at its facility in Fayetteville, N.C., maintains that it is currently capturing, removing and disposing of wastewater that contains the byproduct GenX.
    - EPA's health advisory for PFOA and PFOS combined is 70 ppt. There is no EPA health advisory level for GenX
    - NC DEQ and DHHS are continuing to investigate the levels of GenX in the lower Cape Fear region. The state DEQ developed a "health goal" for GenX in drinking water of 140 nanograms per liter (parts per trillion). This updated health goal is expected to be the most conservative and health protective for non-cancer effects in bottle-fed infants, pregnant women, lactating women, children and adults.
    - On July 17, NC Governor Cooper sent a letter to EPA urging EPA to set limits, revisit the consent order, and require Chemours to submit additional studies on GenX.

- PFAS chemicals lack evaluated, quantitative toxicity information and validated analytical methods. The lack of information and methods makes it difficult for EPA Offices and Regions to make evidence-based decisions regarding potential human health risks from ongoing or future exposures.

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
|---|---|

- Lead: OCSPP/OPPT
- Other: Cross-Agency, including OW, OLEM, ORD, OECA, and EPA Regions 1, 2, 3, 4, 5, 6, 8, 9, and 10.

# NEGOTIATED RULEMAKING: CHEMICAL DATA REPORTING REQUIREMENTS FOR INORGANIC BYPRODUCTS

## SUMMARY:

EPA is in the process of negotiating a proposed rule to limit chemical data reporting requirements under subsection 8(a) of the Toxic Substances Control Act (TSCA) for manufacturers of any inorganic byproducts when such byproducts are subsequently recycled, reused, or reprocessed. This negotiation process is required by TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The objective of the negotiated rulemaking process is to develop and publish a proposed rule by the statutory deadline of June 22, 2019.

## BACKGROUND:

- Under the TSCA Section 8(a) Chemical Data Reporting (CDR) rule, EPA collects data from manufacturers (including importers) on the manufacturing, processing, and use of chemical substances in commerce, for those chemical substances listed on the TSCA Inventory.
- This information supports Agency risk evaluation, risk management, and other programs; it is made publicly available, to the extent possible, while protecting information claimed as confidential business information.
- A byproduct chemical substance is a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture. Because byproduct chemical substances are manufactured for a commercial purpose, this manufacturing is reportable under CDR unless covered by a specific reporting exemption.
- TSCA now includes a requirement that EPA enter into a negotiated rulemaking, which requires forming a negotiating committee (Committee) made up of interested stakeholders, to develop and publish a proposed rule to limit the reporting requirements under TSCA section 8(a) for manufacturers of any inorganic byproduct chemical substances when such byproduct chemical substances, whether by the byproduct chemical substance manufacturer or by any other person, are subsequently recycled, reused, or reprocessed.
- The objective of the negotiated rulemaking process is to develop and publish a proposed rule by June 22, 2019. In the event the Committee reaches a consensus and a proposed rule is developed through the negotiated rulemaking process, a final rule resulting from such negotiated rulemaking must be issued by December 22, 2019.
- In June 2017, EPA established the Committee and invited 25 representatives of industry, States, Non-Governmental Organizations, and Tribes to participate as members (in addition to EPA members).

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- December 2016: EPA published its notice of intent to negotiate and began the process of identifying potential Committee members.
- May 2017: Public meeting held on inorganic byproducts for the purpose of information exchange and to discuss the process of negotiated rulemaking prior to the establishment of the Committee. Notice published announcing first and second Committee meetings.

- June 2017: Committee established, and first Committee meeting held
- August 2017: Second Committee meetings will be held
- September and October 2017: Third and fourth committee meetings planned

## HOT ISSUES:

This negotiated rulemaking has received some trade press, and a small number of public comments on the December 2016 Notice of Intent to Negotiate. Committee members have been active and engaged participants at the public meeting and first Committee meeting, with a few additional members of the public also attending.

Stakeholder interest has largely been supportive of EPA's efforts to move quickly to reach consensus and proceed with the rulemaking. Issues identified by stakeholder and committee members have included:

- Consensus – Requests for increased clarity regarding how consensus must be reached (resolved through Committee subgroup discussions)
- How to balance the burden of reporting with the utility EPA derives from the data submitted

An additional key issue is the significant pressures of short timeframes allotted by the statute and the next CDR reporting period (in June 2020) for finalizing any rule that would result from these negotiations.

## LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT, with a cross-Agency workgroup formed as part of the rulemaking process (including OLEM, ORD, OECA, OGC, and OP).

# ASBESTOS HAZARD EMERGENCY RESPONSE ACT (TSCA TITLE II)

## SUMMARY:

The Asbestos Hazard Emergency Response Act (AHERA) and its implementing regulations at 40 CFR part 763, subpart E, require public school districts and non-profit schools to inspect their schools for asbestos-containing building material, prepare asbestos management plans and to take action to prevent or reduce asbestos hazards.

## BACKGROUND:

- In addition to requiring schools to inspect for asbestos and maintain asbestos management plans, schools must use asbestos professionals trained pursuant to the EPA asbestos Model Accreditation Plan (MAP).
- EPA developed the asbestos MAP for states to establish training requirements for asbestos professionals who do work in schools and public and commercial buildings.
- The AHERA regulations require school districts and non-profit schools to inspect and then re-inspect for asbestos-containing materials in each school every three years; develop, maintain, and update an asbestos management plan and keep a copy at the school and the school district office; provide yearly notifications to parent, teacher, and employee organizations on the availability of the school's asbestos management plan and any asbestos-related actions taken or planned in the school; designate a contact person to ensure the responsibilities of the public school district or the non-profit school are properly implemented; perform periodic surveillance of known or suspected asbestos-containing building material; ensure that trained and licensed professionals perform inspections and take response actions and provide custodial staff with asbestos-awareness training.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- EPA included asbestos as one of the initial 10 chemical substances subject to the Agency's initial risk evaluations under new TSCA. The scope of the risk evaluation uses the TSCA Title II definition and does not include evaluating legacy uses (including asbestos still in buildings), or uses no longer manufactured or imported into the U.S. Asbestos is defined under AHERA as the "asbestiform varieties of six fiber types – chrysotile (serpentine), crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite or actinolite."

## HOT ISSUES:

- Excluding legacy use of asbestos in the risk evaluation has been criticized by some stakeholders.
- The definition being used for the evaluation does not include "Libby Amphibole," which includes primarily winchite and richterite, fiber types not included in the TSCA Title II definition. Libby Amphibole is the asbestos found in the Libby, Montana, vermiculite mine which contaminated vermiculite products. Hundreds of deaths have been attributed to asbestos disease occurring in and around Libby, Montana.
- Vermiculite containing Libby Amphibole is no longer manufactured or processed in the U.S. and is therefore excluded from the risk evaluation.

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
| --- | --- |
| OCSPP/OPPT | ORD, OGC, OAR, OECA, OLEM, All Regions |

# TSCA SECTION 6 RULES: TCE AND METHYLENE CHLORIDE/NMP

## SUMMARY:

- Section 6 of the Toxic Substances Control Act (TSCA) provides authority for the EPA to ban or restrict the manufacture (including import), processing, distribution in commerce, and use of chemicals, as well as any manner or method of disposal of chemicals.
- Trichloroethylene (TCE) in aerosol degreasing, spot cleaning in dry cleaning facilities, and in vapor degreasing:
  - EPA has proposed a regulation under section 6 of TSCA to address the risks to human health identified from TCE in commercial and consumer aerosol spray degreasing, as a spot cleaner in dry cleaning, and in vapor degreasing.
- Methylene Chloride/N-Methylpyrrolidone (NMP) in paint removers:
  - EPA has proposed a regulation under section 6 of TSCA to address the risks to human health identified from methylene chloride and NMP in paint and coating removal.
- EPA's proposed rules made determinations that the chemicals present unreasonable risks to human health, EPA proposed regulatory action under section 6(a) to the extent necessary so that the chemicals no longer present such risks.
- TCE, methylene chloride, and NMP are also included in the initial group of ten chemicals to undergo risk evaluation.

## BACKGROUND:

- TCE is a volatile organic compound (VOC) and hazardous air pollutant (HAP) classified as a human carcinogen. In the June 2014 TSCA Work Plan Risk Assessment for TCE, EPA identified acute and chronic non-cancer and cancer risks associated with TCE use in commercial degreasing and some consumer uses.
- Methylene chloride is a volatile solvent that is a probable human carcinogen used in consumer and commercial paint and coating removal; at least one worker death annually is attributed to methylene chloride in bathtub refinishing. NMP is a developmental toxicant presenting risks of fetal death and decreased birthweight; it is used in consumer and commercial paint and coating removal and is often a substitute for methylene chloride in consumer uses.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- On December 7, 2016, under section 6(a) of TSCA, EPA proposed to ban uses of TCE as an aerosol degreaser and for spot cleaning in dry cleaning facilities as a result of health risks identified in a 2014 TSCA Chemical Work Plan Chemical Risk Assessment for TCE. The comment period closed on March 16, 2017, and EPA received 28 comments on the proposed rule.
- On January 19, 2017, under section 6(a) of TSCA, EPA proposed to ban the use of TCE in commercial vapor degreasing as a result of health risks identified in a 2014 TSCA Chemical Work Plan Chemical Risk Assessment for TCE. The comment period closed on May 19, 2017, and EPA received 544 comments on the proposed rule. This proposed rule and a proposed rule on TCE in spot cleaners in dry cleaning and consumer and commercial aerosol spray degreasing are planned to be finalized together in one action.

- On January 19, 2017, under section 6(a) of TSCA, EPA proposed to regulate NMP and methylene chloride in paint and coating removal. The comment period closed on May 19, 2017, and EPA received 1,401 comment on the proposed rule.

**HOT ISSUES:**

- These actions are the proposed rules taken on existing chemicals under the new statutory standard provided for in the TSCA amendments enacted in June 2016.

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
|---|---|
| OCSPP/OPPT | OGC, AO |

# OSCP SCIENCE COORDINATION OVERVIEW

## SUMMARY:

The Office of Science Coordination & Policy (OSCP) provides leadership on emerging science policy issues, promoting solutions that utilize cutting-edge science such as the application of computational toxicology to endocrine disruption.

## OSCP COORDINATION ACTIVITIES:

- **Systematic Review:** OSCP leads development of the OCSPP systematic review framework to harmonize approaches for the collection, evaluation, and integration of data for human health and ecological risk assessments in OCSPP. OSCP co-leads EPA's Systematic Review Community of Practice (CoP).
- **Computational Toxicology/Tox21/High Throughput Screening & Testing/Alternative Testing Strategies:** OSCP coordinates (for OCSPP and the Agency) the development and regulatory use of computational toxicology tools to increase the pace and quality of chemical safety decisions. [ HYPERLINK "https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-edsp-21st-century" ], or "CompTox", uses computer models and high throughput cell-based methods in place of traditional animal-based chemical testing methods.
- **Scientific Integrity (SI):** OSCP leads efforts to ensure OCSPP's adherence to professional values and practices when conducting, communicating, and applying the results of science and scholarship. Scientific Integrity ensures objectivity, clarity, reproducibility, and utility. It also provides insulation from bias, fabrication, falsification, plagiarism, outside interference, and censorship.
- **Scientific Peer Reviews Conducted Under the Federal Advisory Act (FACA):** OSCP oversees OCSPP's FACA committees that provide independent advice and expert consultation at the request of the EPA Administrator with respect to the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures or approaches for chemicals. [ HYPERLINK "https://www.epa.gov/tsca-peer-review" ] reviews chemicals regulated under Toxic Substances Control Act (TSCA). [ HYPERLINK "https://www.epa.gov/sap" ] reviews issues that are applicable to chemicals regulated under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA).
- **The Endocrine Disruptor Program (EDSP):** OSCP coordinates the development and implementation of the EDSP within OCSPP. [ HYPERLINK "https://www.epa.gov/endocrine-disruption" ] prioritizes, screens and tests pesticides and other environmental contaminants for potential effects on estrogen, androgen, and thyroid hormone systems in humans and wildlife. The EDSP engages closely with other EPA Offices, other Federal agencies, international organizations and outside stakeholders.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- The Science Advisory Committee on Chemicals (SACC) was established December 2016.

## HOT ISSUES:

- Upcoming [ HYPERLINK "https://www.gpo.gov/fdsys/pkg/FR-2017-06-06/pdf/2017-11694.pdf" ] to consider and review the ''Continuing Development of Alternative High-Throughput Screens to Determine Endocrine Disruption, Focusing on Androgen Receptor, Steroidogenesis, and Thyroid Pathways'' scheduled for November 28 - 30, 2017.
- Release of NAS Report "[ HYPERLINK "https://www.nap.edu/catalog/24758/application-of-systematic-review-methods-in-an-overall-strategy-for-evaluating-low-dose-toxicity-from-endocrine-active-chemicals" ]." EPA is reaching out to other federal partners to collaborate on the report's recommendations.

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
| --- | --- |
| OCSPP/OSCP<br>CDC, CPSC | OPP, OPPT, ORD, OW, OGC, OP, OLEM, FDA, NIH, |

# LAUTENBER CHEMICAL SAFTEY ACT SCIENCE ADVISORY COMMITTEE ON CHEMICALS (SACC)

## SUMMARY:

The Science Advisory Committee on Chemicals (SACC) was established in 2016 under the authority of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) and operates in accordance with the Federal Advisory Committee Act (FACA) to provide independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated by TSCA.(see [ HYPERLINK "https://www.epa.gov/tsca-peer-review/science-advisory-committee-chemicals-basic-information" ])

## BACKGROUND:

- SACC is currently comprised of 18 members (see [ HYPERLINK "https://www.epa.gov/tsca-peer-review/members-science-advisory-committee-chemicals" ]), appointed by the administrator from public nominations. Members have expertise in:
    - Toxicology; environmental risk assessment; exposure assessment; and related sciences, (e.g., synthetic biology, pharmacology, biotechnology, nanotechnology, biochemistry, biostatistics, PBPK modeling, computational toxicology, epidemiology, environmental fate, and environmental engineering and sustainability).
- SACC members also have professional experiences in government, labor, public health, public interest, animal protection, industry, or other groups.
- SACC members serve staggered terms of appointment, generally of two to three years duration. If necessary, subcommittees will be formed to supplement the expertise of the 18 members.

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- SACC establishment charter filed with Congress on December 30, 2016.
- 18 current members were appointed by the Administrator effective January 19, 2017.

## HOT ISSUES:

- Potential augmentation of the SACC membership to better address the Committee's objectives and scope of activities.

## LEAD OFFICE/REGION:

OCSPP/OSCP

## OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

# ENDOCRINE DISRUPTOR SCREENING PROGRAM (EDSP)

## SUMMARY:

The Endocrine Disruptor Screening Program (EDSP) prioritizes, screens and tests pesticides and other environmental contaminants for potential effects on estrogen, androgen, and thyroid hormone systems in humans and wildlife.

## BACKGROUND:

**EDSP's objectives include:**

- Integrating data from current and emerging technologies, including computational toxicology and high throughput screening
- Advancing understanding of key events in adverse outcome pathways (AOPs)
- Employing a multi-tiered prioritization, screening, and testing approach
- Minimizing the use of animal studies
- Employing 21st Century informatics supporting data interpretation and decisions
- Promoting transparency and partnerships with a diverse range of partners and stakeholders
- Developing systematic review protocals and for outcomes based approaqches

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- Published the policy stating that the Agency will use high-throughput *in vitro* assays and computational models in the EDSP ([ HYPERLINK "https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0305-0001" ] FRN)
- Validated 18 high-throughput *in vitro* Estrogen Receptor (ER) binding pathway assays and the ER ToxCast™ ER model as alternative to 3 of 11 Tier 1 Screening Assays ([ HYPERLINK "https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0305-0001" ])
- Screened more than 1800 chemicals that have been evaluated using high-throughput assays and a computational model for the estrogen receptor pathway. These data are publically accessible through the Endocrine Disruption Screening Program for the 21st Century Dashboard ([ HYPERLINK "https://actor.epa.gov/edsp21/" ])
- Developed an initial approach and conducted [ HYPERLINK "https://www.epa.gov/sites/production/files/2015-06/documents/120214minutes.pdf" ] of Integrated Bioactivity and Exposure Ratio (IBER) for prioritization
- Completed the [ HYPERLINK "https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-tier-1-screening-determinations-and" ] for 52 List 1 chemicals (50 pesticidal active ingredient and 2 inert ingredients). EPA concluded that additional tests, including certain Tier 2 tests, were needed for 18 List 1 test chemicals
- Published the final [ HYPERLINK "https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-890-endocrine-disruptor-screening-program" ] for EDSP Tier 2 ecotoxicity testing

## HOT ISSUES:

Upcoming [ HYPERLINK "https://www.gpo.gov/fdsys/pkg/FR-2017-06-06/pdf/2017-11694.pdf" ] to consider and review the ''Continuing Development of Alternative High-Throughput Screens to Determine Endocrine Disruption, Focusing on Androgen Receptor, Steroidogenesis, and Thyroid Pathways'' scheduled for November 28 - 30, 2017

| LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS: |
|---|---|
| OCSPP/OSCP | OPP, OPPT, ORD, OW, OGC, OP, OLEM |

# FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICDE ACT SCIENTIFIC ADVISORY PANEL (FIFRA SAP)

## SUMMARY:

The Scientific Advisory Panel (SAP) was established in 1975 under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and operates in accordance with the Federal Advisory Committee Act (FACA) to provide independent scientific advice and recommendations to the EPA on the scientific and technical aspects of health and safety issues related to pesticides. (see [ HYPERLINK "https://www.epa.gov/sap/fifra-scientific-advisory-panel-sap-basic-information" ]).

## BACKGROUND:

- By statute, the SAP must consist of 7 members (see [ HYPERLINK "https://www.epa.gov/sap/fifra-scientific-advisory-panel-members" ]), appointed by the EPA Administrator from nominations provided by the National Institutes of Health (NIH) and the National Science Foundation (NSF). Members have expertise in:
  - Toxicology; pathology; environmental Biology; and related sciences (e.g., exposure assessment, biostatistics, computational toxicology, epidemiology, and environmental fate).
- SAP members serve staggered terms of appointment, generally of three to six years duration.
- For each review, the SAP is augmented by additional experts (known as the Food Quality Protection Act Science Review Board, or FQPA SRB).

## HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- SAP renewal charter filed with Congress on October 17, 2016.
- December 13-16, 2016, FIFRA SAP meeting to consider and review EPA's evaluation of the carcinogenic potential of the herbicide glyphosate; meeting minutes and final report issued March 16, 2017
- 2 current FIFRA SAP members were re-appointed by the Administrator for 1 year effective July 15, 2017.

## HOT ISSUES:

- Nominations from NIH and NSF received in May 2017.
  - September 2017 Federal Register Notice seeking public comments on candidates under consideration.
  - 4 new member appointments needed in 2018: 2 new member appointments by May 2018 and 2 new member appointments by July 2018.
- Upcoming FIFRA SAP Meetings (announced in the Federal Register on June 6, 2017):
  - October 24 to 27, 2017 to consider and review physiologically based pharmacokinetic modeling to address pharmacokinetic differences between and within species.
  - November 28 to 30, 2017 to consider and review the "Continuing Development of Alternative High-Throughput Screens to Determine Endocrine Disruption, Focusing on Androgen Receptor, Steroidogenesis, and Thyroid Pathways."

## LEAD OFFICE/REGION:

## OTHER KEY OFFICES/REGIONS:

OCSPP/OSCP

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